An Inter-Observer Reliability Study: Clinical Photography and Direct Clinical Observation of Plantar Corns and Callus associated with a Nominal Scale Classification Model

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Lastly, I am indebted to podiatry students for engaging with this piece of work, especially those who gave up their Christmas shopping.

Glossary

Terms have been expanded from the main text ‡

Atrophy – Loss of tissue can arise from various processes including infection, excessive pressure and vascular impairment (necrosis). Skin thins as loss of surface arises, which in turn leads to ulceration.

Biomechanical – Broadly considered as the effect of physical forces applied to living tissues, skin, fat, muscle & tendon, bones and joints. There are clinical elements and pure mathematical elements associated with this science.

Bifurcated *callus* **–** used in the context of a plantar metatarsal skin lesion covering two metatarsal heads in close proximity so as to leave observation less clear as to deeper damage and involvement. The centre may be involved between metatarsal heads so the lesion is not a true separate callus.

Callus - an area of skin which is thickened, common to the hands (palmar) and feet (plantar). May arise around heel and on tops of toes.

Corns – discreet areas of thickening within skin, often forming a cone like presentation. The true nature, depth and distribution can be difficult without debridement.

Clavus – associated with a corn; alternative name. See under ***heloma***.

Debridement – the mechanical process where hard skin associated with callus or necrotic tissue is reduced, often around the edges of a wound. Once debulked, the tissue can be better identified and /or new blood flow created to an otherwise poorly supply area of skin and tissue.

Dermatologist – a medical doctor who specialises in skin diseases.

Dermatoglyphics - refers to the formation of naturally occurring ridges on certain body parts, namely palms, fingers, soles and toes.
https://en.wikipedia.org/wiki/Dermatoglyphics

Dermis – made of a high collagen fibrous content that supports essential structures such as nerve element and blood vessels, sweat glands and immunocellular defence and repair cells. The dermis is adhered to the epidermis by the basement layer or membrane. Any cut made through the basement membrane forming the epidermo-dermal junction will lead to bleeding and active nerve signals causing pain.

Descriptor – Used in the context of classification and refers to the text / narrative describing key features of a pathology, such as change in shape, size, density, colour, distribution and other features within a lesion that might suggest deterioration from normal. The descriptor is common to all classification systems, allowing the clinician to interpret between Types, Stages or Grades of pathology.

Digital – refers to the toe (or finger) and locations may relate to the apex (*end*), in between the toes (*inter-digital*), or dorsal (*top*) aspect often associated with the two key joints or the inter-phalangeal articulations which are often fixed or flexed.

Epidermis – the most outer surface of the skin forms a cellular layer that sits above the *dermis*. It is made from a protein called keratin, hence the use of the terms kerat- oma (*swelling*), -osis (*condition*). The layer is generally thicker where optimum pressure points are found, or where the body requires greater stress tolerances. This includes the pulp of toes and fingers, plantar and palmar surfaces of the foot and hand, and the heel of both hand and feet. The arch is considerably thinner. The epidermis is part of a layered structure and the surface is known as the ***stratum corneum***. It is water resistant and hard wearing preventing micro-organisms entering.

Epidermo-dermal junction – the skin is layered and the epidermis formed from distinct layers; *corneum (compactum), granulosum (granular), lucidum (dropped), mucosum (spinous), germinitivum* (*basal*) layer. The basement layer forms a close undulating connection with the next structure called the dermis. Those in parenthesise indicate name changes since 1975. (Haake et al, 2000)

Enucleation – the mechanical process where tissue is removed conically or as a cone by circumscribing the area of interest. Used commonly to remove corns from the skin without breaching the epidermo-dermal junction.

Expert – a person with a high level of knowledge or a skill relating to a particular subject or activity. http://dictionary.cambridge.org/dictionary/english/subject .

***E.* Panel** - a group of people with specific experience in podiatric medicine and surgery each holding higher qualifications with >20 years of *field* experience. Selection in this group included an ability to score >83% correct scores for photographic illustration of lesions.

Extravasation – the material extruded from damaged capillaries under the skin leaks blood content (*haemorrhage*) and so changes colour to a brown-black stain. Some of this relates to the iron pigment and correlates to a type of bruising.

Fibrous *corns* – A nebulous term for a recalcitrant corn which is difficult to debride or enucleate. Such corns are thought to have a greater proportion of fibrous material. The histological finding are often unrewarding, and the clinician needs to look at the deeper tissue layers within any sample taken. It is not unusual to find a viral infection caused by the human papova virus within such a sample of corn.

Field Skills – as applied to this project, a qualified podiatrist usually, or one who has sufficient clinical independent exposure, such as a student in their last year of training. The percentage of clinical exposure varies but should dominate the occupational timetable in a 'clinical or therapeutic' arena with patients[1].

Fissures – a single or series of linear breaches splitting the epidermal layer, and may reach the dermis causing bleeding. Exposed nerve endings create pain. Often associated with dehydrated skin and common to the heel area in the foot.

Heloma – Latin - implying a corn. The word forms the prefix to different types of corns, h. vasculare (vascular), h. milliare (seed), h. durum (hard), h. molle (soft).

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[1] The percentage of direct clinical work was based loosely on the old Whitley Terms for Podiatry in regard to grading where 'high risk' work was considered in percentage terms before the pay award. Agenda for Change (2004) has reflected a different set of criteria. *Skill level 7 - Highly developed specialist knowledge across the range of work procedures and practices, underpinned by theoretical knowledge and relevant practical experience. Skill level 8+ - Advanced theoretical and practical knowledge of a range of work procedures and practices or (b) specialist knowledge over more than one discipline/function acquired over a significant period.* NHS Job Evaluation Source p23 - NHSemployers.org

Hyperkeratoses Hyperkeratosis – applied to increased skin cell turnover as in the case of the epidermal layer. Corns and callus form one example only. Not all hyperkeratoses are synonymous with corns and callus.

Hyperplasia – to increase in size by cellular enlargement, as distinct from hypertrophy.

Hypertrophy – to increase in size by cellular activity; rate of cells present increase.

Hypodermis – can be found below the dermis and contains a high proportion of fat cells (*subcutaneous substance*). The skin, made of the epidermis and dermis, sits on a mattress like structure forming an important mechanical cushion offering body insulation and allowing surface blood vessels to change in response to temperature. The tissue is thickest under the heel, forefoot and toe pulps.

Intractable Keratoma or ***I.P.K*** – the origins are less clear, but usage in podiatry is more likely to have arisen from United States origins. The suffix –oma suggests swelling but the term clearly derives from keratin material. Literature is none too clear but there is an element of interchangeability associated with corns and callus, rather than a single element. In many cases the use of intractable means constant, unrelenting and untreatable as far as corn management is concerned, and therefore could be associated with the more severe forms, causing pain and requiring regular but painful debridement. As with the vascular corn, these can bleed. Keratomata / Keratomas (plural) do not always have a corn element within the callus. Keratoma has not been used within the method to avoid confusion of terminology.

Keratolysis – *pitted* – the keratin is thicker and forms craters within the body of the callus distributed. The origin of the problem may be associated with abnormal moisture build up as in over active sweat glands or periods spent in wet environments.

Kistler force plate – considered as a very accurate method to measure the forces imposed on the body through feet. A thick plate is inset into concrete and four pillars are arranged with piezoelectric transducers capable of measuring a voltage on movement. The voltage is exchanged for a measurement in $n.m^{-2}$. The patient is directed to walk across the plate, often hidden under a panel matching the floor. The Kistler would have little value in assessing callus, only forces that might influence the skin but will not relate to the actual forces across skin as the accelerated body is represented more notably.

Lesion – Any change in biological tissue considered outside normal expectations e.g. blister of the skin, callus, wart.

Liquefaction - a process where material within tissue looses its solid state.

Necrotizing/Necrosis – literal meaning, 'death' of tissue. Part or whole skin looses nutrition provided by the usual blood supply. The cells at that point can no longer sustain their natural function.

Pes cavus – literally 'foot-hole' but used where the arch of the foot fails to contact the surface of the ground across the middle. This leads to a humped appearance of the foot.

Plantar *surface* **–** or sole of the foot is represented by the area of the foot in contact with the ground, but includes the arch of the foot.

Plantar Metatarsal head (*Plantar* – M.H.) abbreviation associated with the inferior surface of the metatarsal which is curved and directly links to the main weight bearing sole of the foot. M.H 1 would imply the first of five standard metatarsal heads covered in thick cartilage and functions within a fibrous plate fitting snugly under the metatarsal.

Planimetry – a system using laser light as in a handheld digital computer for measuring flat surface areas (*Rogers, L C, 2010*).

Pinch callus – A term relative to callus formed on the edge of the foot; apex and pulp of toes, medial or lateral sole and similarly around heels. Epidermal tissue is thickened and creates a ridge often with local vascular damage.

Reliability - Reliability is the extent to which a measurement procedure yields the same answer.

Repeatability – Repeatability is where a similar result can be achieved on more than one occasion.

Seed corns – often referred to as *Heloma Milliare*. These are discrete areas of skin which exist as separate seed like lesions, singly or in multiples (clusters). The cause of the lesion has been studied but build up of cholesterol has been refuted. There is a distinct possibility that such lesions arise principally where skin is most lax (*mobile*) and frequently seen in the skin of the arch, which is non-weight bearing.

Shearing (callus) – The concept of tangential forces across the surface of the skin, thus deforming the tissue, will include an element of friction and rotation as the foot twists during its final phase of contact before the forefoot leaves the ground.

Student Researcher – author and designer of the project, qualified podiatrist (DPodM, BSc) and podiatric surgeon (FCPodS).

Synovial (sacs) – the synovium is a lining with organised secretory cells found around joints and tendons. These structures can rupture, spilling the content that becomes organised by using the same cells. Commonly seen as ganglia and bursae. Referred to in the text by (Whiting 1997). Plate 1.2 shows an abnormal formation.

Tylosis – associated with callus; alternative name.

Validity (validation) – a process of ensuring that the value measured represents the value expected in a method of measurement.

Vascular *corn* – defined probably before Durlacher's publication (1858) and represented by distinct colour change and bleeding within callus at the point where the junction between the epidermis and dermis meet. In many cases, and evidenced from histological sampling, such lesions are associated with a viral infection caused by the human papova virus.

Abstract

Background

Aetiology is not only unclear in regard to plantar corns and callus but debridement as a treatment has limited benefit. Deeper tissue pathology has been discussed in remote terms, with descriptions largely originating from the 18th century. In 1985 a large clinical study of 1700 patients produced a four-point classification method as a bi-product from a research enquiry associated with hallux valgus. After a few citations this disappeared from podiatry textbooks. Classifications using indirect (photographic) observation and direct (clinical) observation have been used for healing in wounds and burns but not for corns or callus. The strengths and weaknesses of classifying skin is discussed.

Aim

While recognising the limitations of photography within dermatology, a four point graded method (Types 1-4) considers the reliability of a nominal classification system where direct clinically observations use pre and post debridement lesions with descriptive text know as a *Descriptor*.

Method

Photography was selected to evaluate observer ratings for classification of corns and callus. The method was divided into clinical (direct) observation, photographic (indirect observation) scoring six colour lesions, and scoring ten diagrammatic lesions using similar descriptors. Fifty-six first and third year volunteer students (unskilled) were used from an undergraduate course in podiatry. Five podiatry experts (skilled) acted as a control to filter out ineligible lesions, such as dry skin, and to grade each Type by comparative use of photographs. Twenty students observed five feet on three patients within a clinical environment observing the Internationally based code of Ethics for research.

Findings

Third year students performed better than first years when classifying ten illustrative diagrams and six clinical photographs. There was little difference in performance between the two cohorts when observing lesions in a clinical environment. Whilst experts relied on

indirect photographic observation, students performed equally well with direct observation, improving over indirect observation. The number of lesions observed before and after debridement was not statistically significant $p>0.10$, $t = 1.561$. Skill and experience appeared to influence reliability, refuting the Null H_o; trend line $R^2>0.9$ for illustrations and photographs, but not for clinical observation with the benefit of debridement; $R^2<0.9$. Weighted quadratic Kappa – *k* was more reliable than percentage counts where values >0.61 were considered as 'substantial'.

Conclusions

Percentage analysis can prove misleading as a measure of observer reliability. Weighted quadratic Cohen Kappa avoids assumptions produced by chance or guesswork. Photographic observer reliability relates to skill, experience, complexity of lesion border and density. Classification is based on *The Descriptor* to provide clarity within the text. Minor discrepancy was not sensitive enough to alter reliability probably because diagrams appeared to support the descriptors. With appropriate tutoring, reliability could be expected to rise. Any values above 83% or *k* = or >0.81 for Weighted Quadratic Kappa would suggest acceptable observer reliability.

Implication for practice

If debridement has limited benefit, podiatry may struggle to make a case for sustained NHS funding for services, especially for higher risk groups and the elderly.

Debridement as a diagnostic aid is less likely to be challenged than short lasting treatment modalities which could be further criticised where underlying aetiology is missed. The use of 'classification' benefits the clinician in charting lesion progress and re-introduction considered beneficial.

Chapter 1

Background

1.1 Corns and Callus

While the sole, or immediate plantar skin surface of the foot has attracted various nomenclature; corn and callus appears to be most frequently used for 'thick skin'. Only the extreme surface increases as hypertrophy‡ takes place. This is observed as yellowing in varying densities. Callus and Corns are derived from changes within the cellular layers of the skin and form part of the family of affectations associated with hyperkeratoses‡[2], (Bristow 2008). Thickening is usually considered a response to external factors, (Whiting 1997), and this precept remains consistent within current podiatry texts (Frowen et al 2010, Yates & Merriman 2012). Laforest influenced British terminology dating back to 1759, and so the reference to the terms corns and callus in existence today has been substantially established (Dagnall 1965).

In the context of this study even latest orthopaedic publications imply a limited form of words to describe callus and corns without elaboration to the extent of observed skin damage.

'Orthopedic manifestations include pes cavus, hammer toes with frequent corns and calluses…' Miller (2016, p.321).

Descriptions refer to the location of callus on the plantar surface although can be sub divided into various groups. Table 1.1 demonstrates the diversity of terminology. Hyperkeratosis can be used instead of the term callus and corns, older terms such as clavus and tylosis appear as historical interest, more in texts than papers. The table by no means represents all sources, while terms unrelated to the plantar foot have been excluded. The **Glossary‡** provides more detail.

A case history emphasises the combination of terminology with location but no indication of extent of skin damage within the callus arises in the first part of the paragraph below,

"A healthy 50-year-old white man presented with longstanding painful plantar callus <u>over the second metatarsal head</u> that required podiatry treatment to remove <u>callus</u>…" Curran et al (2015), p.203

[2] ‡ Terms in the text expanded in the Glossary throughout the dissertation.

The description of callus being considered ‘thick’ often fails to convey any sense of gravitas toward the lesion. However, Bristow & Turner (2002) suggest that capillaries extrude their content leaving a brown-black stain. This can arise whether it is combined with a corn, callus or deep tissue changes associated with ‘extravasation’[‡]. When debrided, the area sometimes bleeds. This could be easily confused with vascular corns (heloma vasculare)[‡].

Grouios (2004) believes that thickening of the skin on the sole of the foot is helpful to the patient initially, but failure to manage serious skin changes can lead to disabling pathology.

Author & date	I.P.K.	Corn / h.durum/helomata	Clav-us	Neuro-vascular corns or H. neurofibrosum	Vascular corns. H.vasculare	Fibrous Corns or seed corns (H.milliare)	Callosity Or callus	Hyperkera-tosis or hyperkera-totic	Tylosis Or Tylomata
Akedemir 2011							☑		
Carmona 2009	☑								
Davys 2005							☑		
Durlacher 1858		☑		☑	☑	☑	☑		
Findlow 2012								☑	
Grouios 2004								☑	
Hofstaetter 2005							☑		
Mann 1973 (T)	☑								
Potter 2008		☑					☑	☑	
Robertson 1985		☑					☑		
Menz 2007/08	☑	☑					☑	☑	
Rubin 1949								☑	
Dawber 2002 (T)			☑					☑	☑
McCarthy 1986 (T)	☑	☑		☑	☑			☑	☑
Yale 1987 (T)	☑	☑			☑			☑	☑

Table 1.1. Diversity of Terms

The table provides an overview of literature from the UK and USA together with primary authors exemplifying terms from 1949 up until the current century. Heloma Molle or soft corn, wart (human papova virus), keratoderma have not been used in this table but do appear in the literature.

Legend

I.P.K = Intractable plantar keratoma.
H (as a prefix) = heloma meaning corn.
(T) given after the author & date refers to text reference rather than from clinical research papers. Latest texts in the UK still refer to terms that originate before the 19th century and so the reader will find that terms overlap.

1.2 Histology

Bristow & Turner (2002) have retained Durlacher's original taxonomy associated with the seed, hard, vascular, soft and fibrous types without challenge. In relationship to inherited forms of hyperkeratosis affecting feet and hands, they accept such conditions have been based upon clinical and histological appearance historically (Ratnavel & Griffiths 1997). The true challenge relates to the tissue of origin for each type of corn rather than just by its visual appreciation.

Carmona (2009) reported that more discrete entities affect corns at a deeper level. These he determined as foreign bodies and used the term Intractable Keratoma or IPK[‡]. The term keratoma seems unique to North American but is used elsewhere. Menz (2008) favours keratomas (Plural: Keratomata) alongside corns and callus. Carmona's definition of an IPK involved a discrete lesion that appears as a corn within a callus. Former material published covering pedal histopathology with staining and description of callus and corns has opened alternative explanations, (McCarthy 1986, Yale 1987). British texts do include histological plates but these are common to skin rather than specific callus or corn origins (Bristow & Turner 2002). False impressions can arise where the skin illustrated is not derived from the plantar foot.

The relevance of histology to the work in this thesis highlights that observation alone cannot validate the origin of callus or corns, or deeper changes. Further discussion is outside the remit of the work proposed, but nonetheless accompanies the need for careful surface classification by observation after debridement[‡].

1.3 Common Management of Corns and Callus

The condition - corns and callus forms key core management of patients in podiatry, (Farndon et al 2006; Merriman 1993). The key to callus management has been delivered by the reduction of callus bulk, known as debridement, and laid out in standard teaching texts, (Turner & Merriman, 2002, Lorimer, French & West, 1997). The use of clinical scalpel technique is taught from an early stage within formal podiatry education, Plate 1.1.

Debridement removes bulk to minimise excitation of nerve endings and discomfort, or deeper tissue damage gaining more notability in higher risk patients. The main *at- risk categories* retain a significant interest within the NHS framework, largely because of morbidity toward ulceration and loss of limb. The opportunities for managing patients outside the at-risk categories implies less choice and greater reliance on self-funding but Whiting (1997) includes a vital observation associated with all categories of feet. Of Synovial sacs, he states;

"Shearing stress, resulting in the development of semi organised synovial structures in the connective tissue the dermis… Such tissue damage occurs as a rupture just below the dermo- epidermal junction, often heloma durum or deep callus…" Whiting (1997), p.136.

As simple callus does not exclude notable pathology, Plate 2.2 highlights problems underlying even simple skin thickening.

Debridement forms a passive 'treatment' and it is debatable whether it can be classed as treatment at all. This form of management only provides comfort for short periods, (Timson & Spooner 2005, Davys et al 2005, Siddle et al 2012, Landorf K B et al 2013), Failed identification of deeper pathology is highlighted by Whiting's significant observation and raises questions about the cost effectiveness of repetitive treatment (Plate 1.2).

Bryan et al (1991) considered a cost benefit analysis or Quality Adjusted Life Years (QALYS) and included podiatry (sic)[3]. The long term benefit derived from debriding callus for patients can be short lived, although does produce high benefit for which we can equate to restored comfort. As part of core podiatry management, Timson and Spooner (2005) and Duffin (2003) mixed callus debridement with orthoses, the latter author featured adolescent diabetic patients. No one method offered a cure for callus, but debridement and orthoses were found to work better when combined.

1.4 Classification of plantar Corns and Callus

The value of observation in planning treatment, beyond an expression of simple terminology and location, seems paramount to good notation.

[3] The study of foot health and treatment is now called Podiatry but previously was referred as Chiropody. Bryan has used the older terminology which was removed in degree courses throughout the UK by the end of the 20th century.

Springett & Merriman (1995) p.209, suggest that "… the use of a classification system enables the lesion to be described precisely and allows the progress of the lesion to be monitored and management evaluated…"

The use of classification together with location and terminology provides a useful approach to annotation of what has otherwise been a benign foot condition inciting minimal interest.

1.5 Reliability, Repeatability and Validity

Ideal observational research falls to testing and re-testing a method or approach to patient management, providing a sense of repeatability. Comparable studies with skin and wound lesions do not exist widely. Some classification systems are assisted by a panel or group of people. Where evidence is limited, new work is required to set out realistic parameters. The subject of callus classification has been made easier by one paper, used to classify corns and callus, (Tollafield & Price 1985).

Given the thirty-year lapse, revisiting the subject of classification seems worthwhile. While repeatability is outside the scope of this project, inter-observation reliability and validation has been considered important.

Plate 1.1. Method of debridement

The standard debridement process to reduce callus is used in podiatry. The reduction of the keratin bulk identifies damage at a lower level where the dermis and epidermis meet (epidermo-dermal junction). This can be referred to as a keratoma or IPK, or fibrous corn. The classification embodies a Type 4 lesion which turned out to have a human papova viral infection following histological analysis under microscope, but also required full depth surgical excision and plastic repair. Although the project does not look at histology, the lack of appreciation of sub-epidermal pathology remains critical as to the limited benefit provided by debridement.

Source - Tollafield, personal clinical slide library with patient permission

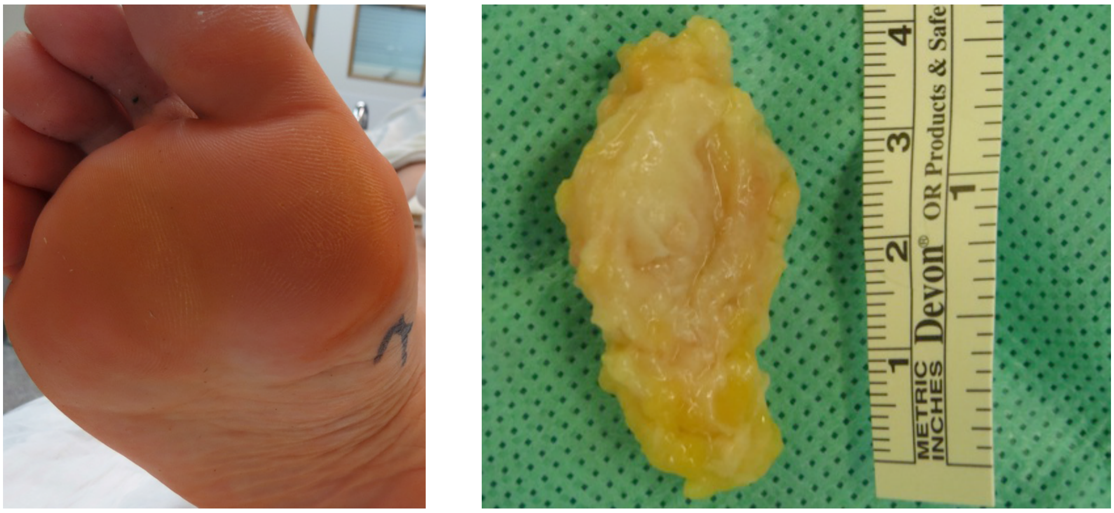


Plate 1.2

Whiting (1997) suggests the relevance of deeper synovial damage below the dermo-epidermal junction. The callus under the first metatarsal head while appearing thin and of little consequence (Type 1) has a necrotizing‡ synovial cyst that has been surgically removed. Simple debridement alone would not provide a satisfactory outcome for this patient, as the hypodermis would continue to result in atrophic‡ damage.

Source – Tollafield, personal clinical slide library with patient permission.

Chapter 2

Literature Review

2.1 Method for Searching

Searches involved mixed sources; private collection of books, journals and personal papers some existing from before 1978. MEDLINE searches conducted through the local medical library at Walsall Hospital and text books borrowed, world wide web searching and Summon, the University of Huddersfield online resource: CINAHL, MEDLINE, PubMed, RCN selected titles, BioMedCentral Open Access.

Amazon on line provided useful references. Google offered access to Abe Books of USA providing rare sources, e.g. Durlacher (1858), Maximillian Stern (1917).

The terms from primary and secondary searches include:

Podiatry, classification (of skin lesions), clinical observation, dermatology and clinical observation, callus debridement, corns and callus, skin lesions, diabetes and foot pressure and observation in teaching.

Reliability, classification, inter-observer agreement, validity, classification of pressure ulcers, photographic assessment, intra class correlation coefficient (ICC), Cohen's Kappa statistical test.

2.2 Key Themes

While the key theme for this project involved observation reliability of a classification method associated with corns and callus, a variety of elements evolved during the study. This allowed method and study protocol adaptation. These have been reduced to three main headings;

(1) Classification models
(2) Callus classification and localisation
(3) Photography

Sub divided into: -

- Models and experts
- Callus classification
- Descriptor for lesions
- Localisation of lesions under the plantar surface
- Observer assessment
- Methods used to consider reliability
- Strengths and weaknesses

2.3 Classification associated with Clinical Observation Reliability

Hop et al (2014) emphasised that reliability has more to do with an assessment method free from measurement error. Subjective scores based on nominal scales, with good definitions, can provide value. The extent of that value can be challenging, and while many parts of health care use classification systems, not all are reliable. Kirk & Miller (1986) suggest that simply believing a principal to be accurate can lead to assumptions creating a type one error. It is for this reason that observer scores require robust testing. Observers are often known as 'raters'. Appropriately assigned scores must be valid and repeatable. There is a difference between reliability and validity, (Sharp, 2004, Dealey & Lindholm 2006). Reliability is related to variation found in a classification system when it is repeated. Ideally, smaller variations imply greater reliability. Inter-observer ratings with more equal reflection suggest better reliability (Beeckman 2007). There is a tendency to use percentage correct ratings for best fit observations based on classification, although, as will become apparent, percentage, while useful, is not always appropriate when measuring inter or intra observer reliability.

"Validity is the extent to which it (*the procedure*) gives the correct answer," (Kirk & Miller 1986), but can also be expressed in terms of achieving the endgame of measuring what it is supposed to measure (Hop et al 2014).

Applying pure validity to callus classification, however, is more difficult because it would be necessary to introduce another parameter into the design, such as histology, ultrasonography or digital planimetry‡. The use of expert panelling offers a form of validation, although the observer raters may not agree, they can reach a consensus. Much of the literature says little about what such agreement MUST achieve, but a number of papers offer an idea about how close observation rating COULD be achieved.

Expert‡ Panelling was used by the European Pressure Ulcer Assessment Panel for the EPUAP classification system itself devised by a group of experts (Bours 1999).

Cohen (1960 &1968) tried to account for some of the errors in measuring observation reliability with percentages. The method has been applied to a number of observation projects with musculoskeletal research (Sim & Wight 2015). Kappa Cohen statistic has therefore been used with some success for categorical data. Furthermore, assumptions made, as with the EPUAP classification method, were exposed after 1452 nurses responded from different European countries. Many nurses believed they had understood how to apply the classification when in fact poor reliability arose due to misunderstanding how to apply the descriptor to wounds assuming different classifications (Beeckman 2007). No prior training was instigated.

The criteria used to establish an observed decision can be influenced by the accuracy of the descriptor. Finding methods to test small variations between descriptors appears unavailable within the subject of 'classification method'. Use of extensive lists of classifications, where the descriptor has large numbers of different options can weaken the method's effectiveness. This was illustrated with eight stages of classification used to describe fingertip injuries (Pinsolle et al 2006).

Sgarlato (1971) attempted the classification for callus based on observing the mechanical effects of shearing forces on pedal skin. His 'in-house' publication covered seven classifications which made effective use of the classification impractical when transferring definition from text to clinic. This illustrates some of the complex descriptor problems that arose with Pinsolle (2006) and Skaare (2013).

Skaare et al (2013) used 10 levels, observing enamel damage in paediatric teeth with photography. The results faired less well when observers (raters) related to degrees of *enamel trauma* rather than *colour variation*. Maintaining a concise classification system was recommended upon concluding their study which agrees with Merriman and Springett's views (1995). The latter nominated six classification groups Table 2.2.

The skin provides a variety of diagnostic features from colour, border variation, symmetry within lesions, and localisation of corns/callus. The approach to visual skin assessment is often known as ABCD (Friedman 1985), with special emphasis around malignant melanomata. Pinsolle et al (2006) emphasises that classification should be precise and reproducible. Shimizu et al (2015) looked to computerised technology to classify lesions which could remove guesswork and reduce observer error. This was found highly applicable for lesions applied to melanoma, basal cell carcinoma, seborrheic keratosis and naevus. Corns, callus or verrucae were not mentioned.

Potter & Aiken (2007) criticised the reliability of corn and callus classification but was weakened by the absence of peer-review and a citable paper. The location of callus seems to raise more interest rather than the quality of the lesion per se. Potter & Aiken considered that heel and digital callus reached consensus but plantar callus failed in this regard. It seems reasonable then to accept variance within opinions but test plantar callus under stricter conditions.

Zanato (2014) challenged skin lesion assessment in the area of the formal ABCD approach to dermatological entities associated with dermatoscopic identification for melanoma recognition. Higher technological systems, as in the case of Shimizu et al (2015) may well be impractical as callus has a greater density, hiding pathology at deeper cellular level where physical debridement is essential. Debridement can still be justified, even if not a valued treatment process, because clarification of tissue damage at the epidermo-dermal junction is much clearer, even to the point where judicious bleeding might arise.

2.4 Callus Classification

Tollafield superimposed his four-staged system for corns and callus (Tollafield & Price 1985), alongside Mann & DuVries's (1978) descriptive six-stage classification Table 2.1, (Tollafield, 2013). This appeared the closest systems to agree prior to his own 1984 study.

DuVries 1978 Descriptor	**DuVries 1978 lesion 1-6**	**Tollafield 1985 Lesion 1-4**	**Tollafield 1985 Descriptor**
Common diffuse callus	1	1	No specific callosity but diffuse or pinch (striated) callosity
Small deep nucleated callus	2	3	Heloma type, durum or milliare without peripheral callosity
Solitary or multiple V.P*	3	NA**	
Circumscribed fungating calluses	4	2	Circumscribed or well defined thickening
Epidermoid cysts	5	1/2/4	Not defined
Intractable plantar keratoma	6	4	Callosity of well-defined nature with well defined heloma lesion

Table 2.1. Early Descriptors for Corns & Callus. US & UK sources

Tollafield (2013) made comparison between DuVries' classification (1978) and that of Tollafield & Price (1985). Two editions later, Mann and DuVries (1992) discarded their list they had called types of solitary lesions.

Key (*VP = verruca pedis. **NA= no applicable)

Merriman & Springett (1995) adapted Tollafield & Price's classification using a 0-6 scale grading. Campbell et al (2002) conducted a study in elderly patients using a 0-6 classification also applied separately to nail pathology, hyperkeratosis, ulcers, infection and pain. Table 2.2 provides a comparison between the three systems where Campbell et al (2002) termed hyperkeratosis: observation, grading scale.

The three classifications appeared as untested empirical interpretations. Merriman & Springett's classification was a theoretical hypothesis while Tollafield & Price (1985) and Campbell (2002) were used in clinical research.

Scale (grade or type)	Campbell (2002)	Tollafield (1985)	Merriman & Springett (1995)
0	Absent, no corn or callus formation	No lesion	No lesion
1	Mild, small corn or light callus formation	No specific callosity but diffuse or pinch (striated) callosity	No specific callus plaque (callosity), but diffuse or pinch callus tissue present or in narrow bands
2	Moderate, average formation in size / thickness of corn or callus	Circumscribed or well defined thickening	Circumscribed, punctate oval or circular, well defined thickening of keratinised tissue
3	Extravasation of tissue underlying corn or callus	Heloma type, durum or milliare without peripheral callosity	Seed corn (heloma milliare) hard corn (heloma durum) with no associated callus
4	Severe, heavy corn or callus formation	Callosity of well-defined nature with well defined heloma lesion	Well-defined callus plaque with definite corn within the lesion
5	Loss of tissue viability	N/A	Extravasation, maceration and early breakdown of structures within the callus layer
6	Tissue breakdown	N/A	Complete breakdown of structure of hyperkeratotic tissue, epidermis, extending to superficial dermal involvement

Table 2.2. Three keratin classification systems adopting similarity to the Tollafield & Price (1985)

One of the advantages in reviewing previous work is the ability to improve and upgrade descriptors. The questions that remain include - how complex to make a system? and how many separate variations or numbers of options should be included? From a consensus from the literature, 4-6 stages can be reasonably included, but without testing the true answer remains unproven.

Tollafield (2013) took his original work with collaborative work of Merriman et al (1995) and dovetailed Type 5 in with Type 4 lesions, but preferred any suggestion of breakdown-ulceration involving dermal tissue to be classified as an ulcer, and thereafter to use ulcer classification only. Nonetheless these systems were starting to consider epidermo-dermal involvement. It seemed remarkable then that this was ignored in later works. The reasons might appear speculative but literature has avoided classification, perhaps based on an uncomfortable belief that it may not be reliable.

Localisation

Following publication of the classification system (Tollafield & Price1985), Merriman Griffiths & Tollafield (1987) presented a new set of results from the same centre using 1223 lesions lesions observed from 459 patients (age-group 20 to 90). Fifty-eight lesion patterns were described but classification was omitted. Nonetheless the study set the bar for lesion studies thereafter in the UK. A number of other authors studied callus location all with respectable numbers, (Springett et al 2003, Potter & Potter 2000). Grouios (2005) used 115 athletes and Spink et al (2009), 301 elderly patients. In the case of Spink the frequency and patterns of callus are represented in Figure 2.1 illustrating an effort to show diversity of localisation. However, even this visual descriptor falls short of the full picture because the accompanying text fails to emphasise that many lesions do not arise over metatarsal heads (M.T.H). Although Spink suggested this diagrammatically, greater emphasis needed to be placed on locational variation. Perhaps researchers do understand localisation differences, but MTH location distinctions are considered too small to be of concern? This recurring theme is in fact a serious omission of true and accurate clinical observation.

Farndon et al (2015) considered 201 patients with variable numbers of corns. The study attempted to correlate an association with pain, disability and quality-of-life. Plantar corns dominated dorsal or interdigital lesions while the fifth metatarsal appeared dominant.

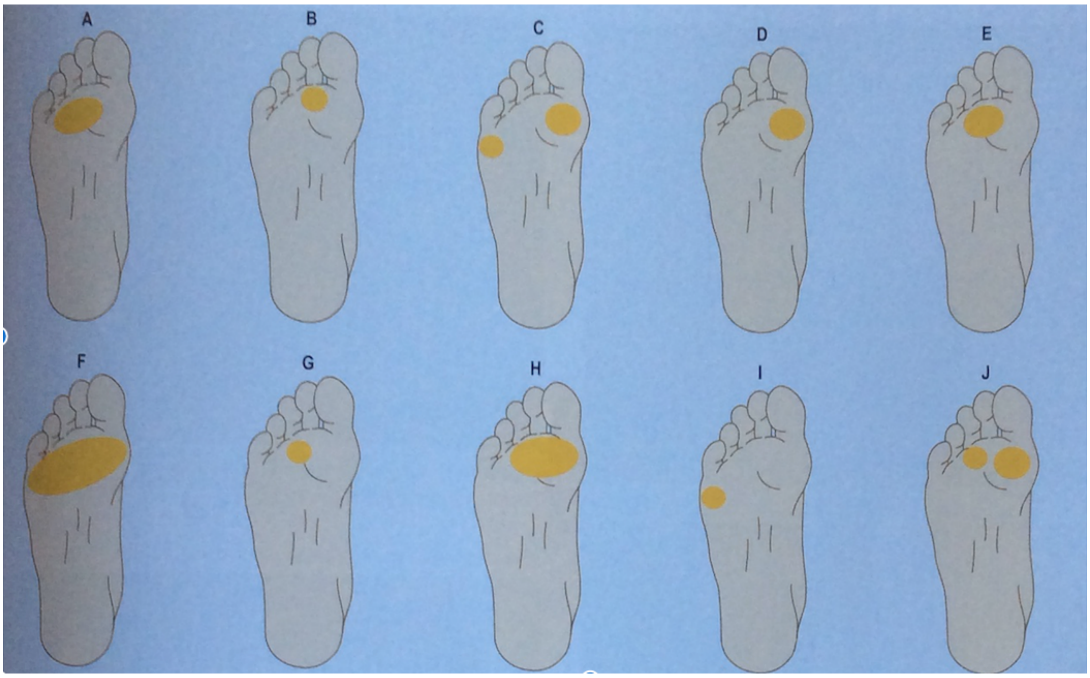


Figure 2.1. Patterns of callus represented for elderly patients

B, E, G, H, J all suggest localisation is not under a metatarsal head but the text fails to emphasise this or the reason for the variation. Since Merriman's (1987) original paper, such patterns do not agree across all studies. Taken from Spink et al 2009 pp.5. Such studies provide the nearest locations while not evaluation that localisation varies for different reasons.

The second MTH, a frequently reported site for callus by authors, as was the first MTH, could not reach consensus. Several studies, Spencer (1978), Dawber et al (2002) used diagrammatic locations bearing little resemblance to presentations seen elsewhere in the literature.

The reason for so many discrepancies in peer reviewed work is almost certainly due to authors using different patient sources and methodology. In the case of Potter & Potter (2000), Springett et al (2003), the main objective was to implement different measurement systems. Potter looked at regrowth patterns of corns and callus studying depth of tissues by ultrasound, while Springett considered a Kistler force plate[‡] for epidemiological left/right handed dominance. Springett did consider lesion measurement repeatability and included margins (borders) as a "transition between pinkish normal skin and yellowish callus plaque…" (pp 6) using a ruler for measurement across its diameter. It would appear while this was defined, no data was used within the paper to show variation. Nonetheless Springett did seem to be more alive to variation of appearance than many of her contemporaries.

The informative value of localisation of lesions supported by a descriptor with notations in case records cannot be stressed. The histological basis for corns and callus remains poorly researched. The difference between a painful corn and verruca (viral infection) still creates difficulties where experienced practitioners can find it hard to agree. This suggests that observed clarification is far from perfect. Classification of corns and callus lesions rely mainly on localisation rather than establishing changes at the epidermo-dermal junction and will resonate commonly within this project.

2.5 Photography

Bloemen (2011) used inter-observer reliability when studying wounds and described various rater skill levels across the study. Of the eight clinicians, four were dermatologists‡, four medium experienced clinicians and three inexperienced students. Digital photographs were used to represent wound healing. PowerPoint™ presented 50 patients to 11 observer raters after a graft was used to re-epithelise the wound. The study thus used larger lesions (wounds) and lower numbers of raters. The intra-observer reliability used a single measurement; an inter-class correlation coefficient (ICC). As with Cohen Kappa, values above .75 represented excellent reliability. The study showed reliability increased with experience, as one might expect. However, the fallibility of the study lay with different treatment methods, causing confounding errors as each surgeon's approach was not standardised. The study used observed % of epithelisation (*coverage of the wound*), while Laplaud (2010) used % of fibrin. This probably led to different results arising between Bloemen's study and Laplaud's.

Localio et al (2006) believed that different age groups and ethnicity were not relevant to the outcome of observations. The classification system used a nominal score based on the depth of ulcers managed by trained nurses. Differences were resolved by consensus from an expert observer-rater panel with six raters, all receiving common training. Unlike other sources this was the only paper to look at specificity and sensitivity factors within the method. It is difficult however to appreciate the value of these factors compared to reliability coefficients (*I.C.C and Kappa*) when linked to observation. Does one need both? Within this study opinion was divided, some agreed more strongly over certain photographs than others. Perfect agreement was reached in 66% of the photos rated for the general observers' use and study.

Studies that use large lesion samples and low observer numbers might be criticised while adequate observation numbers might make a study more significant. It is the observer we should consider relevant to reliability, not large numbers of patient lesions. The contrast to observer size versus lesion numbers might be considered more relevant when conducting a study to determine the best staging within a classification. This is uniformly absent in all sources examined to date.

Beekman (2007) used Cohen Kappa to evaluate the inter-observer reliability, identifying anything below 0.59 as less satisfactory; nurses in this study scored 0.33. The choice between using inter or intra-observer rating is down to the author. Intra-observer rating might be more useful for repeatability studies, currently unavailable for corns and callus, although localisation and reduction of lesions in studies has been carried out (Potter & Potter 2000, Duffin 2003, Timson & Spooner 2005, Davys et al 2005, Siddle et al 2012, Landorf et al 2013).

Soni (2013) considered student podiatrists as observers rated against lecturers. The lecturers were in fact being used as a control. Photographs taken from 28 different coloured plates included callus, human verrucae, fissures, seed corns and melanoma. Verrucae faired less well due to photographic quality, falsely reasoning that verrucae should be easier to identify as they were common. As staff achieved 83-96% accuracy, Soni failed to consider the general difficulties associated with this particular lesion where ‘depth’ is difficult to determine from a colour photograph irrespective of quality of the picture or lack of debridement. Table 2.3 illustrates some of the data pertaining to each student cohort.

	Callus	**Human Papova Virus (HPV)**
Second year	87	68
Third year	91	75
Qualified (lecturers)	96	83

Table 2.3. Percentage of correct observer ratings
Callus and HPV – verrucae for different skill sets in a school of podiatry. Anoj Soni 2013

Observation skills associated with corns and callus do not appear to have been refined in podiatry training. Once suspicion arises that callus is not just callus, and corns are not just corns, additional tests should be used to justify different management pathways. The first part of quality foot care commences with skills and observation. Variations of different cellular manifestation within callus need to be considered further.

Yale (1977), McCarthy & Montgomery (1986), Dockery & Crawford (1997) have included histopathological descriptions, but not always associated with common corns and callus. Science has struggled with the true aetiology of callus. It is acknowledged that there are neurological and vascular anomalies, and human papova virus does have some acknowledgement as a factor in causation. The contribution of callus at deeper tissue level remains uncatalogued. Although cited (Whiting 1977), the contributions are often framed years apart and true collaborative work has yet to link pathology with features of the dermis and in particular hypodermis. Experimental material put forward by computational modelling work has yet to be related to feet, but when ideas of fat deformation are transposed (Weaver et al 2005, Sopher et al 2011, Shoham & Gefen 2012) in the fat associated with heels, it is possible that such modelling could well relate to soft tissue changes in the forefoot.

When we seek evidence as to why corn and callus fails to respond to treatment, modern texts still proselytise on work founded in the 19th and early 20th century. This suggests we have not travelled far from the pivotal work of Durlacher (1858) and Stern (1917) and so remain entrenched at a superficial level.

If we are prepared to link pathological changes at a deeper tissue level with physical and chemical changes, as well as accept the influence of viral infection, then a better scientific lead might prove more profitable in the quest for causation, leading to sustained improvement in the management of corns and callus.

Chapter 3

Aims and Objectives

The subject of corns, callus and *keratoma* requires an in depth study which lies outside the process of a Masters dissertation as it is multifaceted. However, without considering current literature and defining the types of lesions that relate to changes within keratin, without accompanying medical disorders, future progress is limited.

The project sets out to understand and critique literature using an existing classification system, Tollafield & Price (1985), upon which future publications can be developed. The project therefore conforms to the area of work associated with observation which underpins good diagnosis. As no reliability studies have been considered, possibly due to lack of an acceptable classification system, the main aim has been to consider three key aspects. It is suggested as part of the aims that, without a good diagnostic basis, treatment planning will be less effective.

Aim

Indirect photographic observation, while helpful, has limitations and so the use of direct clinical observation has been compared. A measure of improvement will be considered by adopting this technique in 'unskilled'[4] podiatrists.

To use two cohorts of students in a controlled environment to test the hypothesis that there is no difference between ability of student observers, and their rating of lesions. And that there is no difference between indirect photographic observation and direct clinical examination.

That there is no difference in direct observer outcomes between pre-debrided lesions and post-debrided lesions.

[4] The use of the term **skilled** is developed, first in Chapter 4 (Method), and discussed in more detail in Chapter 6 (Discussion).

Objective

By using three parts to the method the research questions have been supported using:

1. weighted Cohen Kappa statistic against percentage photographic representation of observer ratings together with direct clinical observation.

2. an expert panel to consider the use of the term validation in achieving some control of student observed lesions

3. diagrammatic shapes with 'descriptors'[‡] with Cohen Kappa as in (1) and record observer rating outcomes with qualified nurses as an independent group.

4. To identify the accuracy of student observation counts for lesions between undebrided lesions and debrided lesions

Chapter 4

Methodology and methods

4.1 Summary of study design

The main objective of the study is to conduct a method of study using indirect photographic observation and direct clinical assessment with two groups of students from the same educational institution.

Studies cited in Chapter 2 used photographic rating of wounds by observation applied to the method.

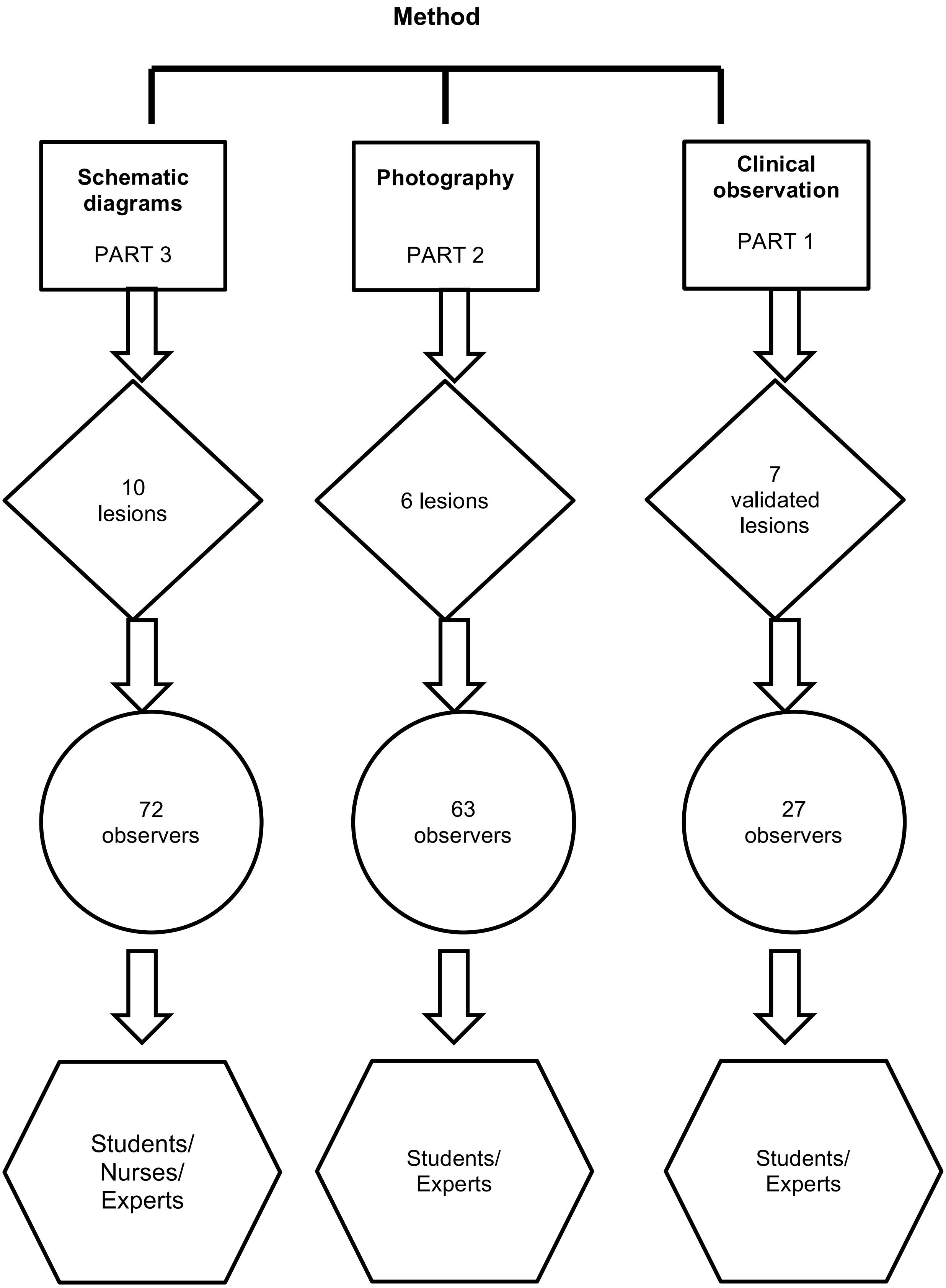
The critical part involved setting the method in a clinical environment while observing strict protocols supported by ethical approval.

An expert panel was established along the lines of Hop et al (2014), Bloemen et al (2011) and Pinsolle et al (2006), where consensus was used to validate the assigned lesions. ‘Expert panel’ observations were conducted through photography alone.

The project method is schematically illustrated in Figure 4.1. The order in which the method was conducted varies to the order presented in this figure.

Figure 4.1.

Schematic summary of project. Inter-observer Reliability for Corns and Callus



Methods

4.2 *Study setting*

Three settings were used; (1) at the University campus - students (2) internet communication - experts. (3) classroom - students.

Nurses worked out of the same outpatient department in a hospital.

4.3 *Subjects in study*

4.3.1 Recruitment of student observer raters (Table 4.1)

In keeping with similar processes, Hop et al (2014), Bloemen et al (2011) and Pinsolle et al (2006), skilled staff were recruited in the same manner as the students. An expert either had clinical experience with wounds (nurses), clinical observation or experience with corn and callus management (podiatry) for a period of greater than five years and at AFC skill level 7 or 8[5]. This group was referred to as ***skilled***. Skill was therefore determined by the length and type of clinical experience.

Two classes of students were selected; first year - recent recruitment and third year - the existing cohort and next to qualify. Both groups were training toward a BSc(Hons) degree in Podiatry. Written explanation outlined the reason for the research and their individual contribution as part of informed consent[6]. The student researcher was not involved with selection and all students were anonymised. A number was allocated so that each student observer-rater could be traced throughout the whole process allowing data to be matched.

Third year students with two years' prior experience were deemed to have some skill, and were referred to as **semi-skilled**. First year students had less than one term of experience and therefore were deemed **unskilled**.

[5] See **footnote 1** covering Agenda for Change (AFC) within **The Glossary**, covering 'experts'.

[6] See **Appendix 1** for the **Consent Form** used.

Most first year students fell into 18-21 age group (40.6%) while the 31-50 mature age group dominated the third year (45.8%). The breakdown of student recruits by age group and previous educational experience is given in Appendix 2.

Both groups were invited to participate in the classroom and clinical methods consisting of three parts, set out below. Fifty-five students completed two of the three parts, while 20 students completed all parts of the method. The classroom group comprised of 24 third year students and 31 first year students. The clinical method consisted of two groups of ten students.

Exclusions

- Not wishing to participate
- Spoiled observation forms
- Lesions including the hallux and lesser toes were removed from Part 1.

4.3.2 Experts

Twenty health care assistants and nurses volunteered to participate in the last part of the method (Table 4.1). Each recruit undertook clinical work in wound management. The nurses were selected randomly by an independent senior hospital nurse. The nurses were used as a control against the student findings, based on their skill in clinical wound observations.

Podiatrists were nominated following a postal/internet study. Five volunteer clinicians were selected from 36 podiatrists by e-mail. Their selection was based on an observer rating equal to or greater than 83% accurate lesion response from photographic slides. Fifty percent of expert podiatrists responded with observer rates of 83%-100%. This provided best validation of the photographic lesions. Beekman (2006) identified 66% correct rating of the classification for non-expert raters while the expert podiatry group returned 22%.

The experts could not attend the clinic because of distance and conflicting work schedules. The consensus was performed blind and the final part of the method used photographs as with the method used by students in Part 2.

Two dermatologists and one scientist (biophysics engineer) were recruited. There was no proscription to achieve a minimum of 83% for the additional three observer-raters. Dermatologists were used in Bloemen et al study (2011) for observing common healing in wounds and surgical grafting. The scientist was an outlier with extensive knowledge of the foot (biomechanics) and achieved a score commensurate to the podiatry raters (83%+). The process associated with the validation of lesions is described (4.4.4).

Observer Rater Group	**First year student** (Unskilled)	**Third year student** (Semi-skilled)	**Nurse observer** (Skilled)	**Qualified panel** (Skilled)
PART 3 diagrammatic relationships with classification types	31	24	20	6
PART 2 photographic representation six cases (six feet), single foot lesions	31	24	0	8
PART 1 Pre and post debridement on three subjects (five feet)	10	10	0	7

Table 4.1. The number of observer - raters recruited to each part of the method

The first and third year student observers remained constant i.e. taken from the same source The student researcher took part as an expert in part 1.

4.4 Method & Materials

General design

The inter-relationship between the three parts of the method involved (Figure 4.1)

(1) Clinical component requiring direct observation of three patients.
(2) Quality colour photographs presented as a PowerPoint^{TM} (six lesions) by indirect observation
(3) Control (diagrammatic) indirect observation

Materials

PowerPoint^{TM} was used in the classroom to illustrate slides for all student raters. Poor quality slides were removed. The colour pictures had good definition, density variation within the callus and the appearance of quality striae (dermatoglyphics[‡]).

A Canon Powershot SX50HS utilised macro settings with standard lighting control. Flash photography was not required. The digital camera was set at the highest definition.

Limited clinical patients were available. After informed consent, three female patients (>60 years of age) volunteered to come to clinic for the study. While the age of the three clinical patients contrasted with Part 2, where patients sampled using photographic slides had a wider age range. The anomaly was not thought relevant.

A lesion chart was provided for all groups (Figure 4.2).

4.4.1 Lesion chart

The lesion chart represented lesions graded as Type 1-4, based on Tollafield & Price (1985) descriptors, taking into consideration shades, borders and shapes within a box. The lesion chart was used to assist the descriptors A & B. All observer raters were provided with this chart to undertake Parts 1-3: -

1. Without a distinct border
2. Where a clear border exists without density changes
3. With small spherical seed like areas arise
4. With both a clear border and deeper density change[7]

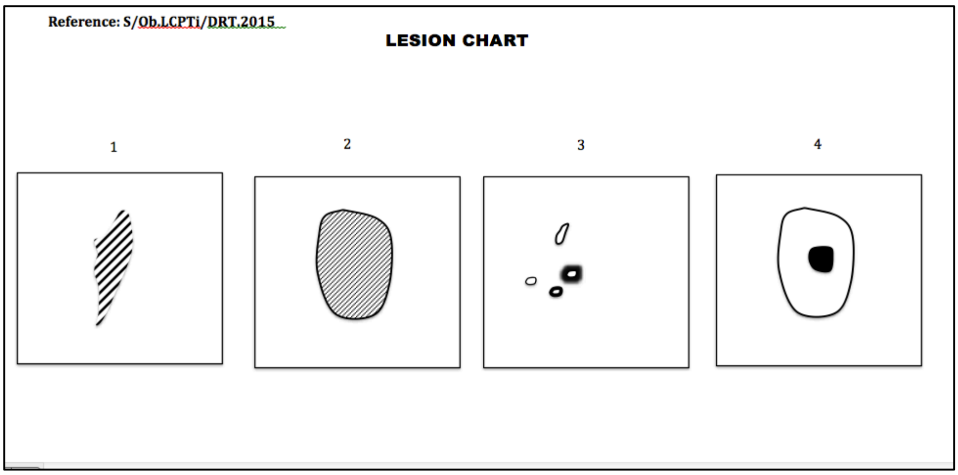


Figure 4.2. The Lesion Chart

[7] Density changes as described took on a different emphasis as the project continued within the part 3 section of the method. Variations in descriptors are dealt with in detail in Chapter 6.6 and Appendix 9 based on the conclusion from these findings in Chapter 4.4.2

4.4.2 Descriptors (Tables 4.2i & ii)

The descriptor guided the observer when scoring a grade for the Type of lesion observed. The lesion chart was designed to assist the observer and has been included as part of the method.

Two descriptors were designed for the method; A & B. The descriptor was modified from the original Tollafield & Price (1985) paper. The grading for each Type of lesion *does* not assume a hierarchical tree and therefore the term staging has been avoided. For most purposes Type 1 is less symptomatic than Type 4. Typing relates to the apparent magnitude of pathology influencing the surface epidermal tissue changes.

'A' was a summarised version of 'B' with the difference being that Type 2 lesions included some 'asymmetric density changes'. In 'B', the detailed descriptor was based not only on the original descriptor D85 - Tollafield & Price (1985), but also a new descriptor D15 – Tollafield (2013).

In 'B', the Type 2 lesion was subtly different and excluded density changes, while only Type 4 lesions included density changes. The objective was to test the different descriptors in a controlled part of the method using just diagrams. Only question (9) of the 10 questions was likely to impose any effect on the rater outcome.

The method included:

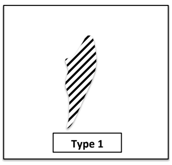
a) retaining Qu.9
b) removing Qu.9
c) allowing raters to use type 2 & 4 equally and count this as a single classification type.

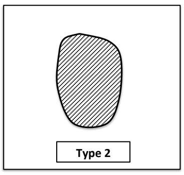
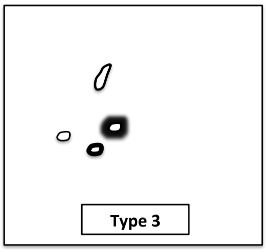
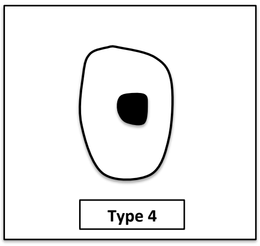
Part 1 and 2 of the method were not affected and relied on descriptor 'B' uniformly across students and experts. Nurses were only included in the part 1 of the method

Type 1	No border definition but retained uniform keratin depth (*shaded*). Ridged or pinch callosity can be considered within the Type 1 definition
Type 2	Border definition was present or partially present with variable keratin depth (*tighter shading with partial or complete border*). No discrete distribution of concentrated keratin is evident in the Type lesion but asymmetric density changes might be observed
Type 3	Concentrations of discrete keratin plugs isolated, or in groups of lesions, generally with a diameter of less than 4 mm (*small circle or oval shapes)* without background callus.
Type 4	Border definition present or partially present with variable keratin depth but demonstrating discrete distributions of concentrated keratin greater than 4 mm diameter (*small circle in larger circle*) within the callus

Table 4.2(i) Simplified descriptor 'A'

Table 4.2(ii) Detailed descriptor 'B'

	Old classification D[85]	**New classification for project D[15]**
	No callus lesion. Normal	No lesion. Even colour, thickness & consistency remain within normal limits for each part of the foot. Heel, sole and pulp of toes may be thicker. There would be insufficient epidermal tissue to debride without affording damage. There are no ridges, fissures or deep tissue changes or lesions within the skin. Keratin lesions associated with other forms of hyperkeratosis <u>do not</u> form part of plantar callus classification.
1	No specific callosity but diffuse or pinch (striated) callosity 	The epidermis is thickened and may have some irregular deeper density changes so as to alter the colour. Callosity shows <u>no border symmetry</u> and maybe diffusely spread without any concentrated area of keratinisation. Petechiae (blood vessels) may be seen or extravasated content. Pinch callosity, also known as ridging, is callus on the edge of the forefoot, occasionally sulcus, heel or apex of a toe. The border may appear isolated as streaky (striated) of callus. While this type of callus may have a defined border it is considered type 1 because it conforms to physiological build up or deformity, and the deeper tissue changes are not involved as in Type 2 or Type 4.

2	Circumscribed or well defined thickening 	A thickness of epidermis forms usually over one or more metatarsals or phalangeal surface of a toe. The border is discrete and may be raised forming a button or disc of thickening. If a partial border is observed, then this is classified as a Type 2 callus. Debridement may be necessary to determine any true nucleation. The underlying callus may be spongy and can only be determined by examination. Areas of flaky skin, complicated with sub epidermal hemorrhage do not constitute a nucleus of tissue and should be disregarded. If debrided the tissue is shown to have broken down, eroded or ulcerated it no longer follows the callus classification but that of a wound.
3	Heloma type, durum or milliare without peripheral callosity 	Usually a discrete circumscribed area, but may be elongated. This lesion has no surrounding callus except at the extreme border where a thickened ring or rim may exist. The lesion is mostly associated with the metatarsal plantar skin where weight bearing is reduced and fat tissue is less pronounced, often with a less tightly bound epidermis. However, the lesion may not be associated with mechanical origins and can occur due to other causes including foreign body infiltration or HPV infection. If this is a suspected HPV then it no longer follows callus classification.
4	Callosity of well-defined nature with well defined heloma lesion 	The callus will have a circumscribed symmetrical or asymmetrical area of greater depth, ridge or greater concentration anywhere within the callus. The size can vary from lesion to lesion-occupying crater like areas after debridement. The nucleus does not have to be limited to the centre and can in some cases manifest within a larger percentage of the lesion. On debridement the base may be damaged as well as uneven in depth. As Type 4 calluses are considered typical of intractable lesions, these are often complicated within the dermo-epidermo junction. Extravasated material, without debridement confirmation cannot be assumed consistent with Type 4 lesions, but there may be density changes within the callus complicated by blood vessel disturbance. The same rule applies if the dermis is breached leading to a wound.

4.4.3. Part 1: Direct clinical observation - before and after epidermal debridement

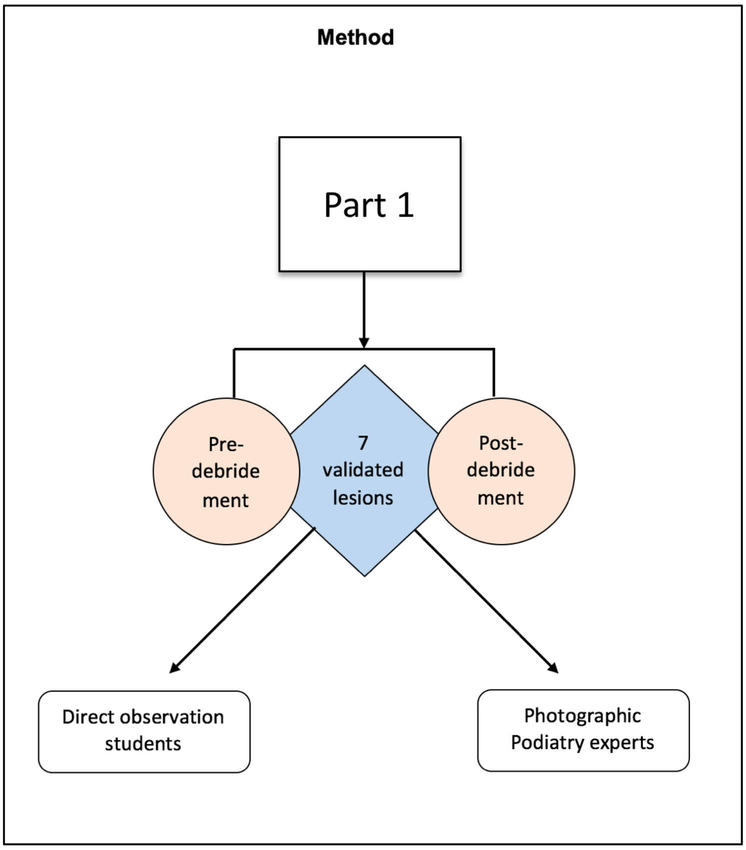


Figure 4.3. Part 1- Method divided into two further components

The research student briefed 20 remaining volunteers using the same descriptors as the experts. Three independently qualified podiatrists undertook patient debridement. Three female patients volunteered five feet with variable lesions. Seven validated lesions were decided by an expert panel to reach an unbiased independent score as well as filtering out minor dry skin (Appendix 9).

The student researcher and a senior lecturer (podiatry) made separate notes of lesions prior to debridement, then invited each student to observe the foot. The senior lecturer was added to the expert panel for lesion validation. Thereafter, the students left the clinic and further notes following debridement were made by the student researcher and lecturer. The lecturer and student researcher did not communicate or agree lesions, or the classification at any time during the observation clinic.

Photographs were taken of each of the five feet before, and then after the debridement took place. The pre and post debridement photographs were sent to the expert panel by e-mail attachment. The post-debridement question was sent after return of the pre-debridement answers with The Lesion Chart - Figure 4.2. This reduced temptation to make comparisons with the pre-debridement material, but did not act, or guarantee comparison with the second phase slides.

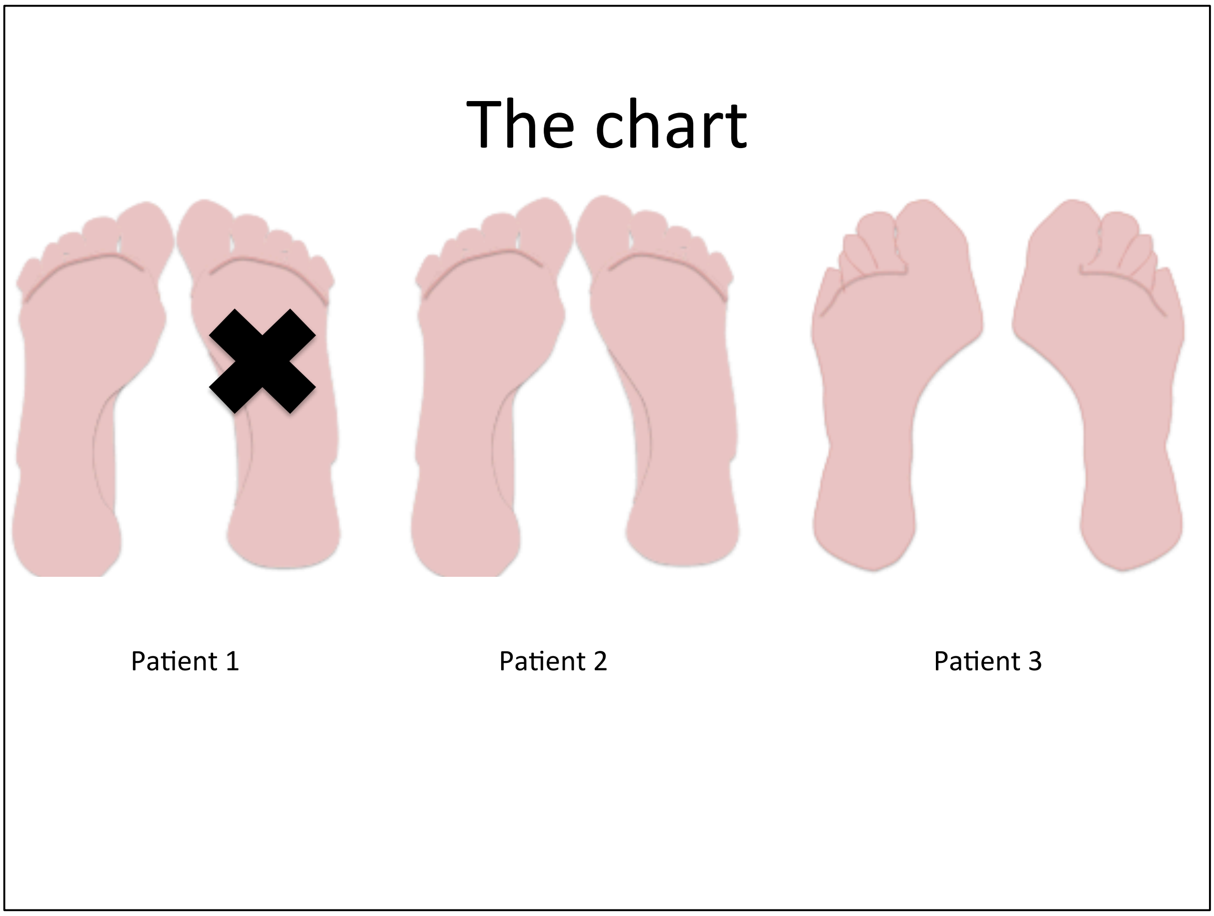


Figure 4.4. Form provided for observer in Part 1 of the method

Student and Expert observers were provided with a similar chart to Figure 4.4 where pre and post debridement lesions were marked within close proximity to the plantar foot corn/callus. Locations were not considered important for this part of the project, only observation of the pre-requisite lesion.

4.4.4 Validating & localisation of clinical lesions with assigned scores (types 1-4)

All parts of the method were managed similarly to remove the need for the student researcher to act as arbiter for any assumed classification score. Seven observers, including the student researcher, and a clinical tutor, provided an objective decision for each lesion. Agreement of location of lesions could not be assumed the same for all observers. Upon collection of all lesion locations, the most reliable lesions were retained, **Table 4.3**.

Validation of the clinical part is considered below as it forms a significant part of the methodology with rationale for lesion selection. Agreement between two sets of lesion-data were required;

pre debridement and post debridement. Examples taken from the pre-analysis selection method are given below upon which critical decisions of lesion acceptance were made.

1) Zero (0) represents an unrecorded lesion by an observer. If the greater number of observers assigned no lesion the location was removed. For example, for seven experts; 1-0-0-0-0-0-0. In this case the lesion was considered too low to grade, or unimportant to record.

2) If the agreement was equal, so as to provide no clear lesion identity, the location was removed. For example, seven experts record 1-0-1-2-1-2-2 where there were equal assigned lesions agreed and one not, the lesion would be excluded as majority consensus was absent.

3) The only variation to this approach related to analysing the descriptor in the case of question 9 which equated to diagram 'I', in this case both options were retained.

4) Dominance would be considered effective in the case of seven expert responses where lesions dominated any other lesion recorded; for example, 4-4-4-2-2-4-4; the assigned lesion Type 4 was used.

CLINICAL SUBJECT	CASE 1	CASE 2	CASE 3
Location of plantar lesion Right foot	MTH 4	MTH 1 MTH 3	MTH 2 MTH 3
Location of plantar lesion Left foot	None	MTH 4	MTH 2/3

Table 4.3. Lesion Location Validated by Expert Panel

Expert panel derived lesions produced seven dominant plantar locations in Part 1 of the method. Each site (below) is approximated to the nearest drawing by the experts. MTH = metatarsal heads as closest representation for replication purposes. These are not accurate locations only schematic representations.

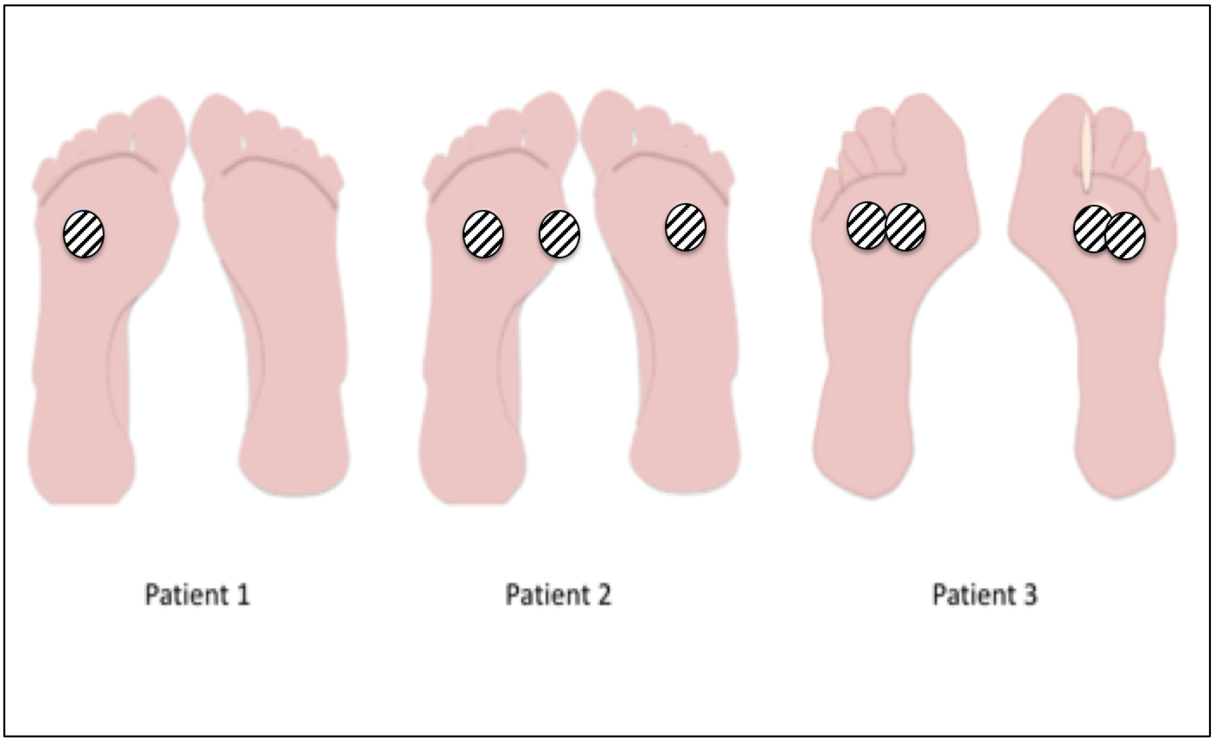


Figure 4.5. Illustration of the dominant lesions approximated to the location selected by the expert panel for comparison (not to scale).

4.4.5 Method (Part 2): Indirect Photographic Observation

Photographic slides/plates form the most frequent method used for many wound studies. The slides were presented by PowerPoint™ to allow uniform observation. The slides had been pre-tested and shown to independent audiences Tollafield (2013). Nurses were not included in this part of the assessment.

Six colour 2-D lesions were provided. Some lesions were marked 'debrided'. Classification Types were to be inserted into the right hand column (Table 4.4). The location of each lesion was specified and not left to chance so all the observers could focus on the same lesion without distraction.

Patient consent was collected in each case by the student researcher from previous clinics. All cases were female aged between 35-65 years of age.

Figure	Location	Classification
1	Metatarsal head Debrided	*To be inserted for each location*
2	Forefoot undebrided	↓
3	First toe Undebrided	↓
4	Second metatarsal Undebrided	↓
5	Third-fourth metatarsal Debrided	↓
6	Fifth metatarsal partly debrided	

Table 4.4. Observer Assessment form for plantar callus in Part 2.

Instructions: *To be used with PowerPoint*

Please look at the six colour plates and for each plate assign one classification that best fits the clinical picture.

Ignore any other lesion other than the one described in the central column.

4.4.6 Part 3- method: Indirect (controlled) diagrammatic observation of lesions

The objective of the method (part 3) was to remove any influence of colour and density but retain distinctive shape and location. Ten feet were illustrated with one lesion per foot in Figure 4.6. The student had to assign the correct lesion Types 1-4 to each foot shown for lesions A-J. The students used descriptor 'B' and the nurses and podiatrists used descriptor 'A'.

Question 9; lesion (I) was deliberately obtuse showing density changes in dark shading to represent deeper skin changes as found in patients. The border was ill-defined.

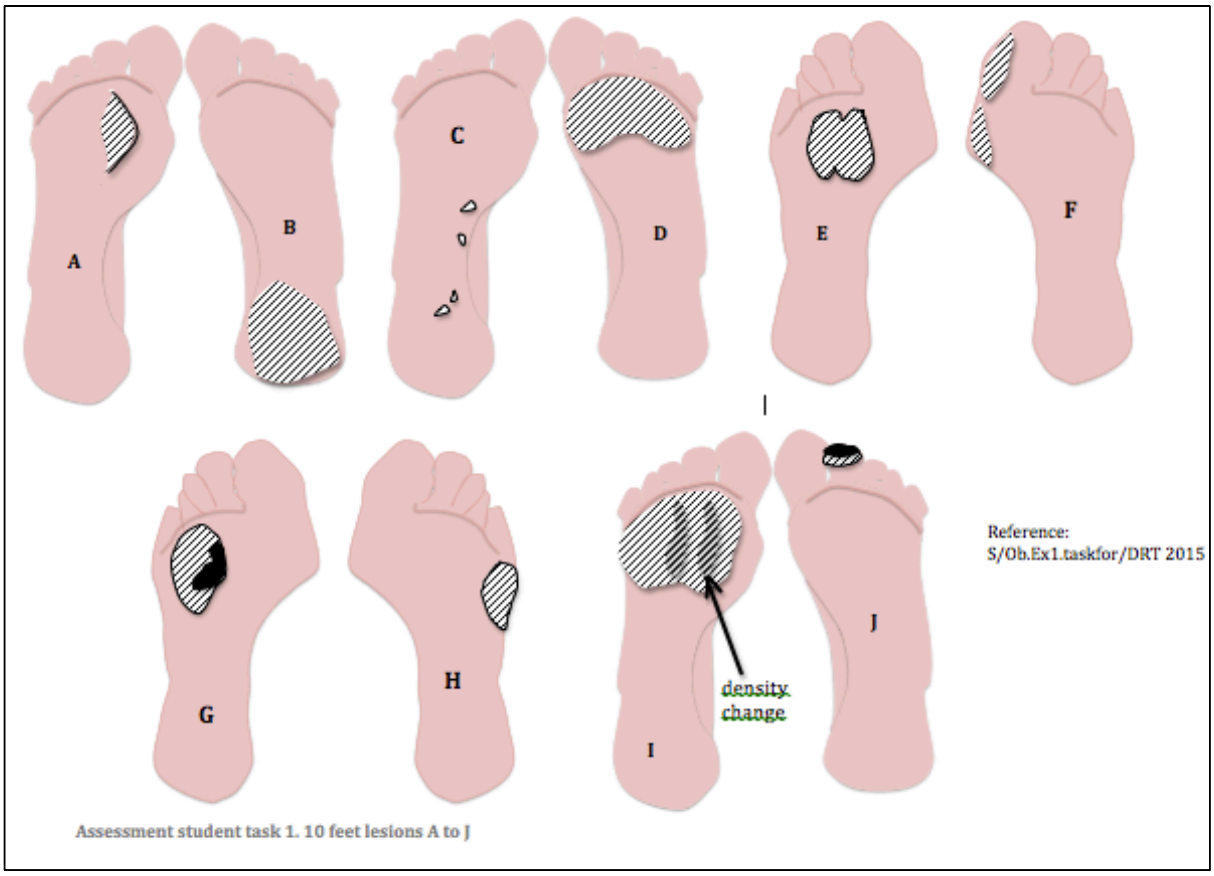


Figure 4.6. Diagrammatic illustrations A-J

N.B in figure 'I' shows no border but does represent density variation deliberately added to make the lesion more complex for 'Typing'. The lack of border was an oversight in the design and added to testing the difference in descriptors between Simple (A) and Detailed (B) – Tables 4.2i&ii

Reference Number _________

Instructions: Please look at the ten feet in the diagram provided labeled A-J. Fill in the table below using the best fit classification 1 to 4. Ensure that you ONLY allocate one number per foot. You may keep the diagrams and chart but hand in this form after completion.

Figure	Callus type 1-4	Figure	Callus type 1-4
A Partial border (*second metatarsal*)	**2**	**F** Two similar lesions (*great toe*)	**1**
B *Heel* with no border	**1**	**G** Single complex *metatarsal heads* 3-4	**4**
C Four lesions of the same origin but different shapes (*arch of foot*)	**3**	**H** Single lesion border (*fifth metatarsal*)	**2**
D All *Metatarsal heads* across ball of foot without a border	**1**	**I** Shows density changes (*whole ball of the foot)*	**2/4**
E Bilobed lesion outline (*metatarsals*)	**2**	**J** Single lesion second (*apex toe)*	**4**

Table 4.5. Diagrammatic lesions should be compared to the Lesion Chart (Figure 4.2) and the descriptors Tables 4.2i&ii).

Experts could not agree on ***Lesion I*** (question 9) and so student raters were therefore allowed to select Type 2 or 4 for one of the analyses using Cohen Kappa k statistic.

4.4.7 Statistical analysis and data

Data was returned and entered onto a Microsoft, Excel ™ spreadsheet. Cohen Kappa (1960) was used to consider reliability of data submitted between observers. A two-tailed student's t test was used to consider if the null Hypothesis would be accepted or rejected between pre and post operation location counts.

Kappa statistic was selected to analyse reliability for observer ratings on a nominal, or ordinal scale (Sim, J & Wright C C, 2015). The weighted form was used. Reliability was then used as an expression of the value of the k statistic calculated. While percentage of agreement might aid reliability, percentage calculation does not take into consideration such agreement that arises by chance or guess work.

Kappa - k therefore provided a measure of true agreement as a proportion between that achieved and what was possible. A contingency table was formed so that frequency of agreement and disagreement could be calculated for each lesion, Type 1-4. While linear weighted Kappa was calculated, quadratic weighted Kappa (WQK) was more sensitive and used for majority of analyses.

Landis & Koch (1977) considered the strength of agreement for a Kappa coefficient 0.81-1.0 implied an almost perfect state, 0.41-0.60 moderate, 0.21-0.40 fair and 0.10-0.20 slight (Sim, J & Wright C C, 2015).

4.4.8 Consent and Ethics

4.4.8.1 Guidelines used in subject selection

Consent ensured that no harm would result from any action taken in conducting this research project. Much of modern day ethical guidelines arose from the workings associated with first the Nuremburg Code, thereafter the Declaration of Helsinki, issued by the World Medical Association (1998), (Schuklenk, 2000)

No vulnerable subjects were involved in the patient or observer (student), or expert group. No treatment was provided, or withheld by any person associated with the project. The normal expectations of care and duty within the clinic were upheld. This took the form of debridement by trained podiatrists.

Beauchamp and Childress (1994) have impacted upon the standard of clinical research over the last twenty years ago. The attractiveness of their bioethical system of proposals covered four main principles delivering either direct benefit without disadvantage or prevention from withholding essential treatment (Schuklenk, 2000).

These principles were applied to the observation project ensuring that all subjects involved were volunteers and invited to ask questions, as well as given justification for their involvement. Within the context of observer involvement, such contribution would add beneficially to their education as elements of testing mental response was involved. No judgement was created within the process as all observers completed their responses autonomously. The volunteers were able to withdraw at any time. Where patients were involved, their normal process of treatment for their callus was completed as usual. Students were not disadvantaged by any omissions or commissions to their course of study.

4.4.8.2 Evidence that ethical rules were applied

The study was approved by the Human and Health Sciences Postgraduate Course Ethics panel at the University of Huddersfield.

Each person in the study was provided with informed consent. This covered all the observers. No data was introduced into the study that had not been designed for the explicit purpose of recording the observations of students. No payment was exchanged for the service to patients on 15th December 2015.

Informed consent provided explanation (Appendix 1- *example of student consent*), withdrawal without obligation and respected each individual decision. When ethical provision was applied, the two class cohorts of 85 potential students – only observer 57 57 (67%) agreed to attend the classroom exercise. Of those who preferred not to attend clinic, as this interacted unfavourably with the period set for the clinical study, 20 (23.5%) observers remained from the original group, which worked out as 35% from the observer cohort.

A detailed proposal was submitted to the tutor initially with the pre-requisite forms and information per University requirement for ethical scrutiny. Safety and confidentiality were to be observed at all times. The use of photography was only localised to skin and maintained patient anonymity without personal identification. Students were anonymised to the student researcher and only relevant data recorded.

4.4.8.3 Project Resources

The study relied upon a registered clinical setting, attention and recruitment of suitable patients with callus, a digital camera and photocopying for forms. The statistics package SPSS was accessed at the University for part of Kappa statistical analysis.

No sponsorship was involved in this study.

Chapter 5

Findings

5.1 Introduction

The results of the three-part method are presented. Data reflects results associated with an inter-observer reliability study between student observers[8] and an expert panel, presented in tables and bar graphs with brief explanation. Where material analysed did not form the main research question, these have been commuted to the Appendices.

Chapter 5 is divided into headings and sub-headings.

Part 1 – Direct Clinical observation

Lesion numbers & counts

Part 2 – Indirect photographic observation

Part 3 – Indirect (controlled) diagrammatic illustrations

Student Observers

[8] Demographic data can be found in (Appendix 2). Photography versus diagrammatic lesions (Appendix 6)

5.2 Part 1*. Direct Clinical Observation*

Method Part 1	PRED	L	Q	%	PSTD	L	Q	%	Difference %
	Expert	0.653	0.680	79.1	**Expert**	0.562	0.568	74.5	-4.6
	Year 3	0.395	0.454	57.4	**Year 3**	0.481	0.540	65.2	+7.8
	Year 1	0.397	0.438	56.3	**Year 1**	0.532	0.555	84.9	+28.6

Table 5.1

Represents data for the clinical observation weighted Kappa & percentage of correctly observed lesions. L= linear and Q = quadratic weight Kappa. The difference is only shown for PSTD values. Students improved their performance on PSTD review.

PRED = pre operative debridement. PSTD = post operative debridement

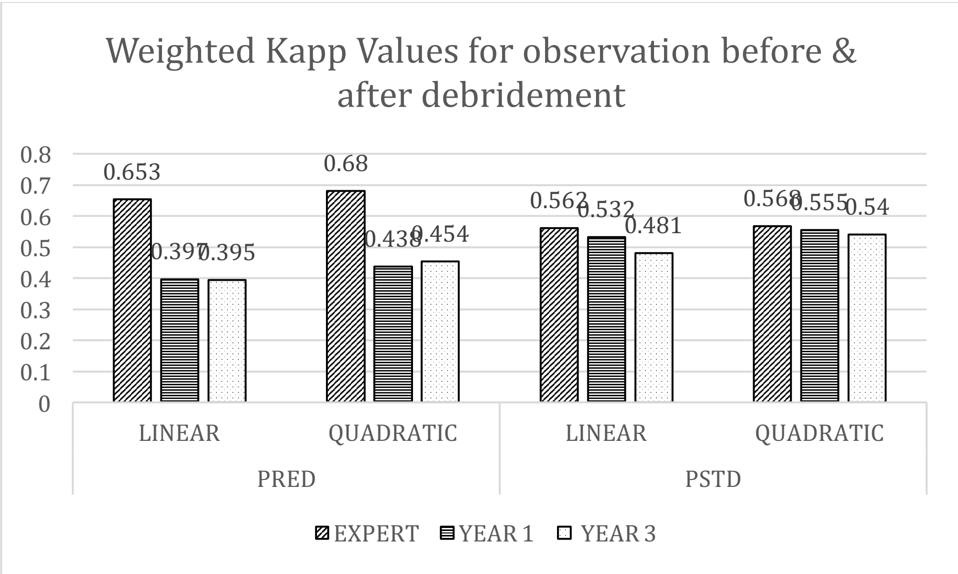


Figure 5.1

Weighted Kappa values for first, third year students and experts for clinically observed lesions where experts used photographs of the same feet as students. PRED and PSTD.

METHOD	Diagrammatic lesion	Photographic lesion	Clinical lesion
Student Yr. 1	0.58 (53%)	0.33 (42%)	0.56 (85%)
Student Yr.3	0.73 (55%)	0.62 (56%)	0.54 (65%)
Expert Podiatrist	0.97 (93%)	0.80 (70%)	0.59 (75%)

Table 5.2

Comparing the results for all parts of the method (Table 5.2) unexpected outcomes are revealed. The clinical lesion is represented by post debridement only

Students improved between pre and post debridement so the Null Ho was rejected as the alternate H_A suggests better definition arises with debridement, especially at deeper levels allowing optical differentiation. The experts did worse at post debridement which would be contrary to expected practise, but did better observing pre-debridement photographs (Figure 5.1). These results will considered in Chapter 6.

5.2.1 Lesions - numbers and counts under controlled method

The number of lesions counted in Part 1 - clinical observation varied widely from 7-17. While this has been explained in chapter 4 and 6, once filtered, the number of lesions was controlled. By using the expert panel, common lesions should ideally correlate with the most frequently observed lesions annotated by the two student groups. Figure 5.2 brought 26 observers (experts and students) together in a histographic representation.

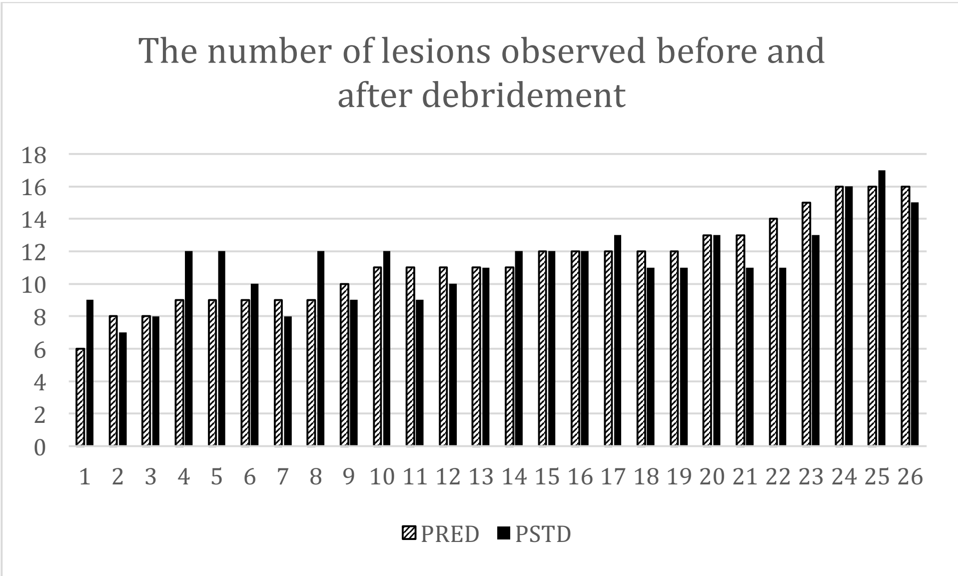


Figure 5.2

Shows Pre-operative debridement (PRED) shaded and post-operative debridement (PSTD) solid for 26 observers (Student observers = 20, Experts = 6).

	PRED	PSTD
Total lesions available	140	140
Lesions not recorded	6	1
Marked but not assigned grade 1-4	8	1

Table 5.3. Location of lesions observed before & after debridement

Seven dominant lesions were selected from a wide range of observed lesions (7-17) which provided 140 observations uniformly recognised by student observers and experts. This is represented in the Table 5.3.

Pre-operative debridement (PRED) and post-operative debridement (PSTD) for 26 observers (Student observers = 20, Experts = 6).

5.3 Part 2. Indirect Photographic Observation

Order of Lesions Part 2	**A**	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**Dominant Classification type**
1	3	3	3	3	3	3	2	3	3 (3)
2	1	1	1	1	1	1	0	2	1 (1)
3	4	4	4	4	4	4	2	4	4 (4)
4	1	2	2	2	1	2	1	1	None (2)
5	2	4	4	4	4	4	4	2	4 (4)
6	4	4	4	3	4	3	3	2	4 (4)

Table 5.4. Expert assigned scores for photographic lesions in Part 2 photographic observation.

Table 5.4 illustrates validation of photographic lesions. Lesion 4 (Type 2) proved more difficult amongst expert raters. This consisted of a lesion with a partial border under the second metatarsal head.

The original assigned score is shown in parentheses. None implies no agreement met. A-E = podiatrists. F = scientist, G & H dermatologists

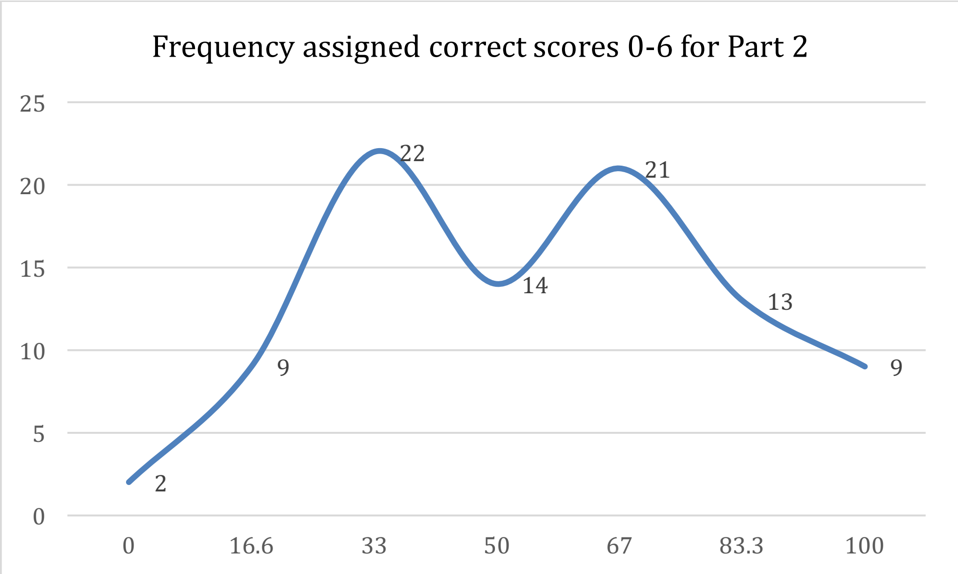


Figure 5.3: Photographic observation with percentage returns on the horizontal axis.

Bimodal frequency graph showing correctly observed single lesions 1-6 for part 2 of the method based on percentage for 90 observer raters - experts & students

Students were asked to respond to the likely grade of lesions. Two students scored zero out of six possible correct scores, while most scored 1+. Majority of the observers achieved 33-67% of the correct scores possible with 22% scoring 83.3% or above. All groups involved with the project were combined to show a bimodal trend. This was compared to all podiatrists who were screened or selected as experts, dermatologists, biophysics engineer and students (n=90).

Part 2 method photographic			
	Linear weighted Kappa	**Quadratic weighted Kappa**	**Correct observations**
Expert	0.699	0.795	70.2%
Year 3	0.503	0.615	56.3%
Year 1	0.263	0.325	41.9%

Table 5.5: Analysis of observer raters for photographic methodology using Quadratic Weighted Kappa & observed percentage frequency

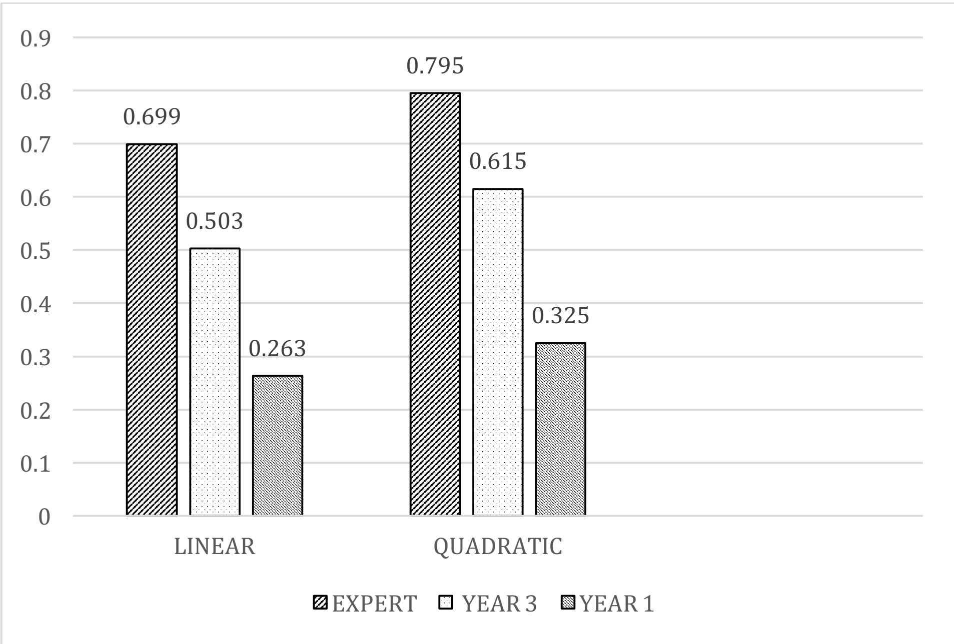


Figure 5.4: Photography - Quadratic and linear weighted Kappa data for inter-rater reliability represented as a bar graph

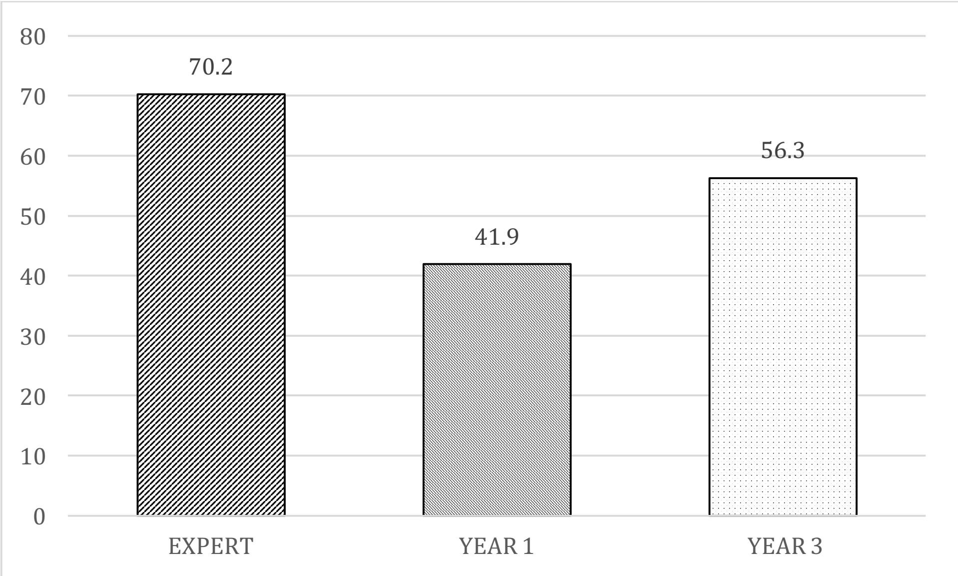


Figure 5.5: Photography - percentage of correctly assigned lesions for observed raters as a bar graph

Observations by percentage have been contrasted with weighted Kappa coefficients. It would seem reasonable to expect a classification system to achieve a high level of observer agreement, but the data included poorer results from two dermatologists. Excluding dermatology data, expert podiatrists in the study had achieved 83.3%.

5.4 Part 3 – Indirect (controlled) Diagrammatic Representation of Lesions

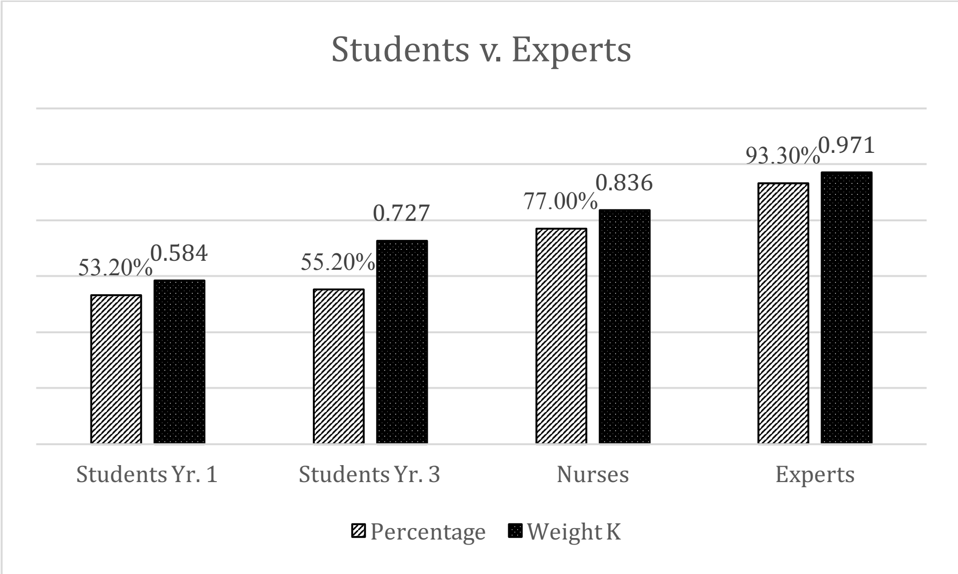


Figure 5.6 Students, nurses and experts (podiatrists)

The bar graph illustrates an expected trend of observer outcomes in percentage terms against Weight (quadratic) Kappa (WQK) for Part 3 Method concerned with diagrammatic comparisons of lesions Type 1-4. Weighted Linear Kappa was also calculated. Inter-Class Correlation Coefficient (ICC) was not used in the study.

Group	Number correct over number observed	Percentage correct	Linear Kappa	Quadratic Kappa
Students Yr. 1	158/297	53.2%	0.469	0.584
Students Yr. 3	132/239	55.2%	0.568	0.727
Nurses	157/204	77.0%	0.762	0.836
Experts	56/60	93.3%	0.942	0.971

Table 5.6

The values of correctly assigned lesions are shown against those observed for Part 3 (diagrams). Weighted Kappa values and percentage of correct responses with linear and quadratic applications of the K value.

5.4.1 Student observers

Percentage photograph observed correctly	**First year student**	**Third year student**
To nearest whole %	42	56
WQK	0.33	0.62

Table 5.8

Percentage observation accuracy podiatry students When viewing photographs against weighted quadratic Kappa (WQK) statistic.

< 0	=	Poor
0.1 – 0.2	=	Slight
0.21 - 0.40	=	Fair
0.41 - 0.60	=	Moderate
0.61 – 0.80	=	Substantial
0.81 – 1.0	=	Almost perfect

Table 5.9

Translating Cohen Kappa correlation (Sim & Wight 2005)

Part 3 method	A	B	C	D	E	F	DOMINANT
A	2	1	2	2	2	2	**2**
B	1	2	1	1	1	1	**1**
C	3	3	3	2	3	3	**3**
D	1	2	1	1	1	1	**1**
E	2	2	2	2	2	2	**2**
F	1	1	1	1	1	1	**1**
G	4	4	4	4	4	4	**4**
H	2	2	2	2	2	2	**2**
I	2	4	2	4	2	2	**2/4**
J	4	4	4	4	4	4	**4**

Table 5.10. Validation of lesions by six expert observers.
Part 3 - method observer rater scores - results varied for lesion (I).

Observer	Control questions	Linear	Quadratic
Expert	unadjusted	0.942	0.971
Expert	Qu. 9 removed	0.938	0.971
Nurse	unadjusted	0.762	0.836
Nurse	Qu. 9 removed	0.810	0.735
Yr 3	unadjusted	0.568	0.727
Yr 3	Qu. 9 removed	0.571	0.735
Yr 1	unadjusted	0.469	0.584
Yr 1	Qu. 9 removed	0.456	0.584

Table 5.11. Adjusted Part 3 method for diagrammatic lesions

A-J shows selective removal of (I) against unadjusted responses to show the effect of an altered descriptor on rating scores.

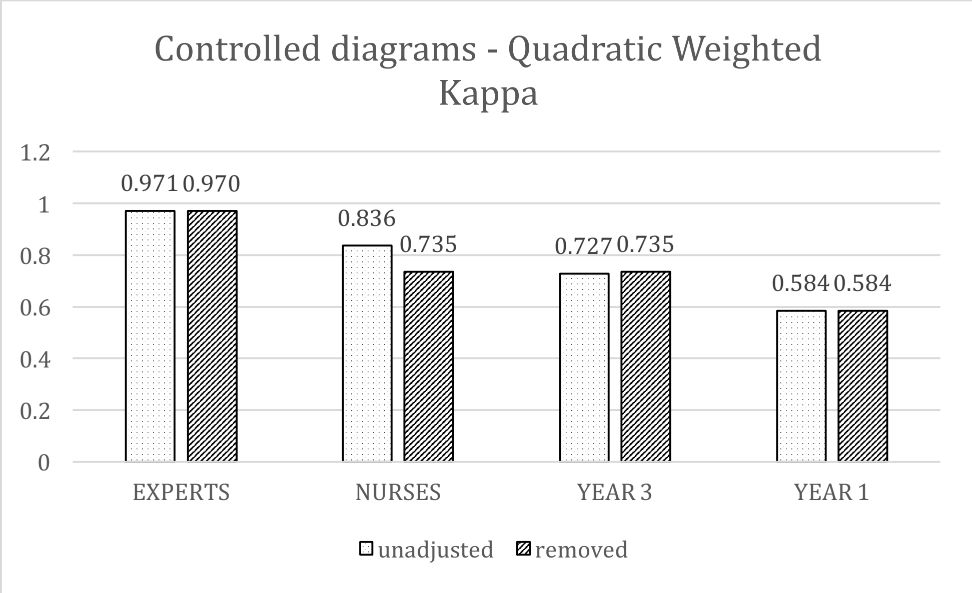


Figure 5.7

Descriptors altered where question (9) relating to Lesion (I) was removed. Shaded as a bar graph, showing changes with *weighted quadratic Kappa coefficient*

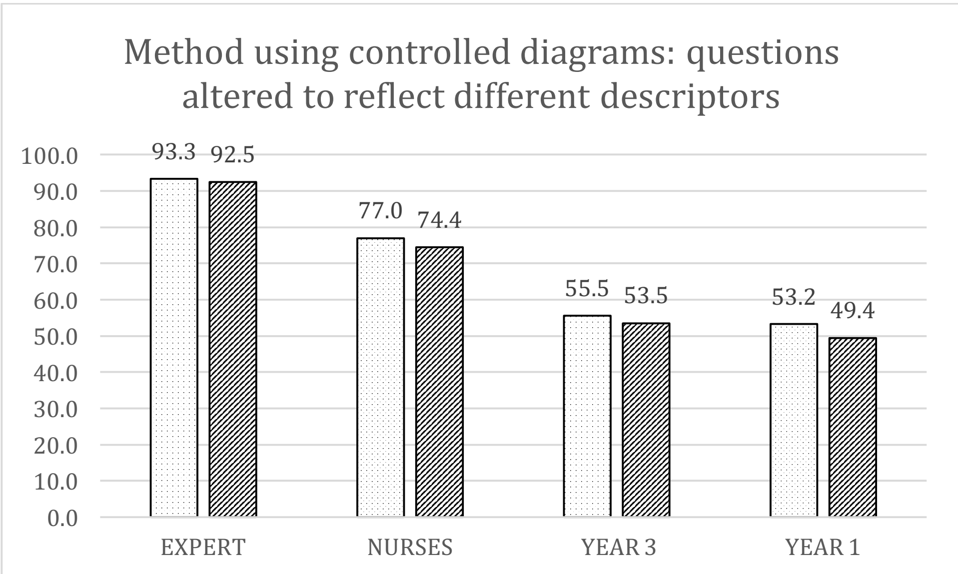


Figure 5.8

Descriptors altered where question (9) relating to Lesion (I) were removed. Shaded as a bar graph, showing *percentage changes*

Chapter 6

Discussion

6.1 Summary

This chapter discusses the findings based upon tables and figures in chapter 5. Consideration is given to each part of the method (chapter 4) and supportive literature (chapter 2). Classification design was found to be related to the quality of the descriptor for each lesion 'Type' assigned. Measurement of reliability between observer raters favoured weighted quadratic Cohen Kappa as opposed to percentage counts.

The hypothesis upon which the research project was designed made comparison between two approaches when assigned a numerical grade using four nominal options called a 'Type' to corns and callus originally proposed by (Tollafield & Price 1985). Each stage, 1-4 was independent of each other.

Strengths and limitations have been considered within a prospective method, highlighting weaknesses which could impact upon future clinical healthcare models for corns and callus, especially within the NHS[9]. Improvements in nominal classification reflect the difference between *direct* clinical observation of plantar corns and callus, *indirect* photographic plates and diagrammatic illustrations, evaluated between first and third year student cohorts.

The impact on podiatric practice is discussed with reference to podiatry moving away from the concept of debridement of plantar corns and callus as a treatment. Greater emphasis associated with diagnostic predictors would ideally offer renewed research hopefully improving outcomes. This could only arise if treatable lesions are graded around low, medium and high chances of success. While the project does not conclude this as a primary finding, any future development should include this as a paradigm.

6.2 Direct Clinical Observation

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[9] N.H.S or National Health Service established 1947 in Britain. The structure and service provision is heavily underpinned by political influence, target drivers based on economics with external regulators such as the Care Quality Commission (CQC) and NICE (National Institute for Health & Care Excellence) playing a role is how healthcare is delivered. Hospitals outside the NHS are not exempt from regulators. The shift of funding methods has varied between different political administrations. Podiatry, as with many professions, has been affected by cut backs and great concern has been voiced by Age Concern to retain support for elderly patients who rely on repetitive callus debridement for comfort and mobility. Campbell (2002)

While photography offers a common method for wounds, no evaluation has been applied to corns and callus. Problems associated with this method of assessment involves trying to differentiate two similar lesions using a flat, or 2-D representation or a 3-D image without the benefit of direct palpation. It was hypothesised that direct clinical observation might improve the chances of observer reliability over photographic plates. Students observed callus lesions in two modes; undebrided and debrided. The expectation that there was no difference between first and third year student cohorts was accepted in general terms of the Kappa statistic. In terms of percentage representation for correctly assigned scores to lesions, this would appear more so for post debrided observation. Such a hypothesis could only be tested upon students as the experts could only observe photographic representation of the same clinical lesions.

The belief that third year students possessed higher skills was not sustained as the first year performed equally as well. Table 5.2 combined all data for students with experts. This contrasted with other parts of the method, such as illustrative diagrammatic comparison, where a lower skill base did show a trend toward greater accuracy with higher skills.

Data are considered for both pre-debridement and post-debridement modes. Given that inadequate deep definition can arise within callus until the surface has been reduced, the underlying elements of pathology cannot be judged accurately. For an individual clinician more clinical information should theoretically arise from post-debridement, but when comparing clinical observations by photographs, experts showed that they were better able to assign a ‘Type’ to the lesion before debridement, WQK = 0.7 for pre-debridement, versus WQK = 0.6 for post debridement.

Post debridement observation was 4.6% less reliable for experts. It is doubtful that this is truly statistically significant at this percentage value as the expert population was small, making statistical testing less meaningful. The project did not have the benefit of direct observation by experts, but it is hypothesised that in such circumstances experts would improve their score and better unskilled observers. Experts performed better in all other parts of the project as expected and consistent with the literature. Bloemen (2011) used 11 observer raters with different skills experience, including three inexperienced students. He found that reliability increased with experience. Reliability associated with observation arising with similar experience between the two student groups in this study does hold true in general. Previous experience was broken down into seven categories (Appendix

5.A) but did not lead to any conclusions. Because detailed analysis is limited to small numbers, further study using a greater student population might benefit.

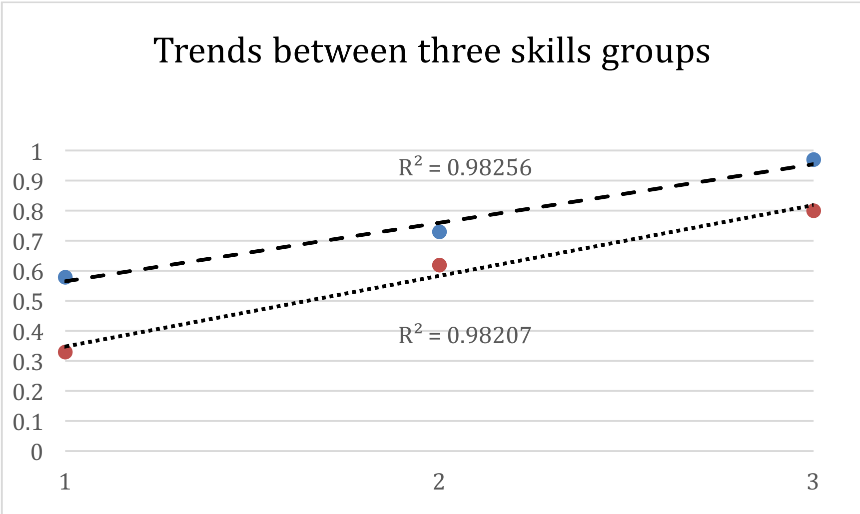

Figure 6.1.

Hard dashes **(blue markers)** represent the diagrammatic illustrations tested, while the dotted line **(red markers)** represent the photographic observations. Kappa values (0 – 1.0) are shown on the vertical axis and the relative experience is represented as (1) first year, (2) third year (3) Experts, along the horizontal axis. Nurses (WQK= 0.84) were omitted as there was no 'time related skill' to podiatry

The trends between skill levels (Figure 6.1) appears to hold true for the illustrative diagrams (R^2 = 0.98256) and photographic parts of the method (R^2=0.98207), but not so for direct clinical observation. Relative trend line values demonstrate an exponential increase in Weighted Quadratic Kappa from first year to qualified podiatrists. Expectations of skill do influence outcomes when compared to a level playing field. In the last part of the method, the trend line broke with the traditional idea that a third year would perform better than a lower skilled first year (R^2=0.10714), not illustrated.

The reasons for the similarity, or small difference between the first and third year in part 1 of the method could be associated with many factors. The groups had equal numbers and were equally motivated, having given up a free period to participate in the clinical based project. Fundamental data concerning age, gender and previous experience was difficult to interpret for so few. The student researcher believed that the small difference was down to the fact that the task contained similar elements for both parties and the improved performance, by the first years, was by chance rather than prediction.

Therefore, any student motivated to attend such a session could do equally well whether they were a first year, second year (not studied) or third year. The gap would increase with greater field skill exposure, so that a third year student in their final semester, or a qualified podiatrist, would more likely show improved performance. The second year students were excluded as the predicted difference between skill levels would be harder to evaluate.

Both the method of calculating reliability and assuming significance to percentage measurement was an important finding. The type of statistic used in the project was commonly agreed amongst all peer reviewed papers (Chapter 2). The difference between actual observed data versus expected data forms the basis upon which Kappa functions, using a contingency table of frequency of results for each lesion Type. The percentage value gives the number of observed results against expected results without accounting for the number of times a particular score was allocated within the group being studied. The percentage gap between the third and first years for post debridement state was not as wide as suggested when Kappa was calculated. The reasons for the different performances between the two years cannot be considered significant because Yr 1 WQK = 0.56 and Yr 3 WQK = 0.54, although 20% percentage difference favoured first years. All other data suggests that the skills between first and second year vary but more so when photographic observation was used. When the students observed the lesions in the pre-debridement state, Yr 1 WQK = 0.44 and Yr 3 WQK = 0.45 with a perceived 1.1% difference now in favour of the third year.

These findings are not conclusive and further study might help identify whether the trend could be repeated or refuted by considering repeatability. First year students did seem to improve their Kappa scores for observation between part 1 and part 2 of the method, while the third year suggested a smaller difference.

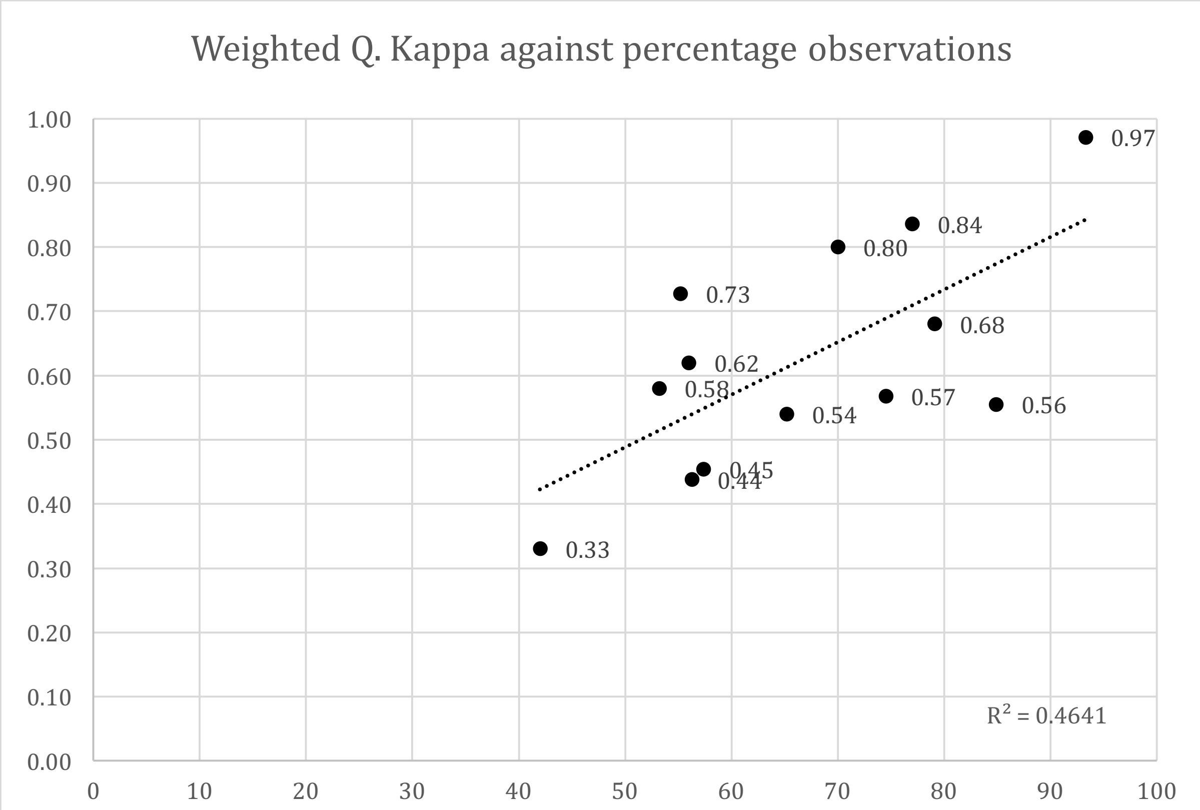

Figure 6.2.

Kappa (weighted quadratic) values do not correlate to percentage values as might be thought likely. The dotted trend line R^2 = 0.46 shows that there is no linear relationship as expected because Kappa uses a contingency table based on how all results are distributed with agreement between observed and actual values. As these Kappa & percentage values come from all parts of the method, it would not be expected that each part could be compared. This serves to highlight the potential for percentage analysis to misrepresent reliability, or to have a direct relationship with Kappa statistic.

Evidence supports better student reliability with clinical observation over photographic representation. The experts' observations based on photographs were 'substantial' (WQK=0.80) compared to the clinical observed lesions transformed into equivalent photographs (WQK = 0.57 - post-debridement). When photographs were observed pre-debridement, (WQK = 0.70). The value of photographs is not as reliable in the hands of less skilled clinical observers. Direct observation is affected by areas unrelated to clinical skill but might rely on *pre-classification tool* tuition. The project did not allow tuition as part of the method but is recommended as an important approach to improving understanding and application of any new classification tool.

It would appear important that any distinction between debridement modes is recognised to avoid predictable errors when using lesion classification for callus.

Dry skin patches, border distinction and variable density proved the biggest observational anomaly. Quality of colour variation within a lesion or a wound is important, so that identification of border definition and deeper tissue discrimination needs to be achieved. Before debridement, the skin may look negligibly affected, but after debridement, a false border can be created. Such a feature was related to the operator debriding the lesion. Traditionally, callus is debrided to blend with the surrounding skin, but many 'operators'[10] leave edges. This is irrelevant as far as the outcome is concerned for the patient. Within this project, variable post debridement border appearance could cause observational obfuscation, i.e enhance a border or rim. This feature can be seen in Appendix 3; B & C - right hand picture column.

Further study, using the classification model, would require filtering out dry skin areas by extending the classification, as in Appendix 10, which could form part of practice change and implementation i.e Type 1 for dry skin. This would ensure podiatrists recognised such a feature without accrediting it to pathology or further suspicion.

Theoretically, the distinction in recognising a corn over callus is not difficult as shown by Soni (2013). When asked to place a corn or callus into four categories based upon presentation, the element of skill rises, but so do confounding factors. Clinicians not only use visual appreciation, but touch and feel, smell and sensory perception as temperature and skin textures change. Subtle levels of redness, dark, light and border differentiation can easily be missed in photographs and this is why melanoma do less well where observation is reliant on colour and tones alone (Zanatto 2010). If we remove the benefit of one or more senses it seems reasonable to expect variation in results. Experience can usually be expected to arise from diversity of clinical exposure and increased patient case numbers, usually related to a period of time. No one lesion is the same and epidermo-dermal junction (EDJ) pathology varies widely, contributing to greater difficulty in assigning lesion Types.

While Soni (2013) suggests higher observer returns for corns and callus, verrucae fair less well. Low percentage scores for verrucae were uniform across three observer groups when compared to callus, seed corns, melanoma and fissures. Soni puts the variation down to poor photographic quality and yet the experts performed adequately. There is a case that his reasoning should have considered the influence of variation in density

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[10] The use of the term 'Operator' has been used here to define someone performing skin debridement. This appeared as part of the Student Researcher's period of undergraduate training between 1975-78.

change throughout a lesion. The skin striae (dermatoglyphics) and sub-epidermal vessel disruptions may define a verruca, but in some cases the presentation is similar to a vascular corn or even a standard corn presentation shown in Figure (Plate) 1.1. These changes arise at the EDJ and often share no single pattern. Debridement assists the clinician but even then no guarantee can be made that a viral element is not present, this can only be achieved by histopathological microscopy and is outside the scope of general podiatry.

Skill, based upon experience and lesion Typing, may provide the answer to such variation, but it also indicates that clinical examination may reach a finite point where lesion differentiation cannot be made conclusively, whether by direct observation or from photographs. In this regard there is no contention that the use of a classification system will answer the clinician's problems and isolated, such a method is not absolutely reliable.

The standard protocol associated with undergraduate training for podiatrists involves undertaking superficial debridement to compare pre-debrided epidermis with post debrided epidermis. When using photographs alone, the observer is faced with less dynamic interpretation than from direct observation, as one expert describes his experience with the classification model used in this project:

> "Defining whether there was a border became the issue for me after receiving the colour plates. Also I was less sure whether I should be classifying it as hemorrhage (sic) rather than Type 4 heloma after reading the definitions. The lesion under the hallux was suddenly a cause of uncertainty once I got the more detailed definitions." Expert Rater 21/11/15

There are practical problems undertaking clinical research of this nature. Low numbers of patient subjects with the difficulty of recruiting sufficient observers at one location contributed to methodology difficulties. Only until such comparative direct clinical work is completed could the classification system, applied within this project, reach a greater level of robust assessment. Parallel wound studies often used larger patient numbers; Bloemen (2011) used 50. Observer numbers were more critical for corn/callus study. In regard to lesion diversity, the inclusion of larger patient subject groups in a future study might be more critical. Recruitment of patients with sufficient diversity of callus will continue to raise challenges within education and training. Dwindling numbers directly attending clinical training centres are uniform in England, as the student researcher found when considering other podiatric training centres.

The use of 'Detailed', versus 'Simplified Descriptors' became more significant when considering the foundation of the corn and callus classification system for observation. This is described in further detail under section 6.6.

6.3 Lesion Identity and Counts

While observers can record the appearance of lesions, comparative group observation associated with lesion numbers or counts distributed on the plantar foot was evaluated. The range of isolated lesions identified between pre-debridement ranged from 8-16, and post-debridement from 7-17, 23.1% showed no change (6 observers). Thirty-four percent (9 observers) demonstrated reduced lesions observed after debridement, and 38.5% (10 observers) observed an increase in lesions. In one case the lesion Appendix 3, B suggested that callus under metatarsal heads coalesces, making counting difficult. In this case the *bifurcated*‡ lesion could be counted as a single lesion.

The null hypothesis was not rejected as the difference between both groups was not significant $p>0.10$, $t = 1.561$ using a two tailed paired t test. The seven dominant lesions selected from a wide range of observed lesions (7-17) provided 140 observations which appeared uniformly recognised by student observers and experts. This is represented in Table 5.3. This intra-study finding could be useful within the field of training to test observational skills. Unless guided, as in the second part of the method, where lesions were specified, the interpretation of what constitutes a lesion varied widely between all observers, including experts. Filtering lesions became necessary and selected by consensus i.e agreement of >50% selection. Dry skin, an old scar featured on one patient and all digital lesions were excluded (Appendix 9.A).

In order to establish a classification, a descriptor should cover all possibilities, but dermatological lesions unrelated to surface pressure or EDJ damage can obfuscate the clinician's selection. Variations such as verrucae[11], fissures and pitted keratolysis‡ must be excluded to avoid extending any classification unnecessarily. Furthermore, once the EDJ is breached, thus forming first an erosion, then an ulcer, a different system of classification should be assigned as new pathology enters the equation. It may be reasonable to avoid using any classification where too many conditions become enveloped under one 'umbrella' system. It could be argued why not use the older terms

[11] Determination of a viral infection (verrucae) cannot always be excluded by direct observation without histology. Lopez & Kilmartin (2015)

alone, highlighted in Chapter 1, Table 1? The suggestion that such terms are made obsolete would be unlikely to meet favour, neither would this benefit the clinical records where most of the classification would be directed as part of annotation of clinical history and examination. Classification does not directly relate to named diagnosis but would provide a lesion grouping because of the wide variation of clinical presentations. The prognosis and outcome could be based upon such a classification.

6.4 Indirect Observation with Photography

Photography is common to part 2 and 3 methods. The quadratic weighted Kappa allowed tightening of the statistic over linear weighted Kappa, which was more robust than unweighted Kappa (not used in this study). Linear Kappa statistics have been shown in the results (Tables 5.6, 5.7, 5.12 and most figures). A weak or strong percentage observation, even though close to the accepted observed score, does not always correlate with a weak or strong Kappa (Figure 6.2). Only one citation favoured percentages when using photographs (Soni 2013).

Wound classification observer studies have been used by expert panels to assist observation of other raters. Weighted Quadratic Kappa (WQK) statistic assists with the question of acceptable level of reliability and improves the differentiation between poor, moderate and good observation scores (Table 5.9). While a score of 67-83% might be helpful, or an arbitrary value of 76%, taken as the mean between 67,83, WQK suggests 0.61-0.80 offering ‘substantial agreement’ (Sim & Wright, 2005). While studies have been conducted with pairs of nurses for ulcer classification rating (inter-observer) k = 0.81 – 0.97, when working independently the values dropped to k = 0.49 (Beeckman 2007). Podiatrists work alone usually.

Our cohorts worked independently, although there may have been some vicarious sharing of knowledge. Other studies, (Bloemen et al 2011, Hop et al 2014) have concentrated on Inter or Intra-class correlation coefficient (ICC) but no additional comment can be made about the validity of ICC over Kappa. In the case of photographic reliability results, values were higher for experts at 0.83 and 0.87 (Hop et al 2014), and as a mean, 0.91 (Bloemen et al 2011). Inexperienced observers reached a mean >0.68. In contrast, Beekman (2007) found nurses scored 0.33, suggesting any value below 0.59 was less satisfactory for wound observation. This might be explained by a diversity of wounds presented to a large observer group (1452 nurses) demonstrating a wide variation of scores.

Methodology could not be compared to observation of corns and callus although values of 0.45 – 0.75 were 'fair to good' (Bloemen et al 2011). Wide values however suggesting 'fair to good' offer limited help, but Hop et al (2014) do at least suggest that >0.80 is considered good. Where ICC and Kappa values >0.8 this might provide some sense of acceptable value status as far as observer rating is concerned, and might be proposed as a benchmark for classification.

In no case did authors comment about the impact of classification models in terms of incorrectly assigned observations for wounds. Reliability with observation within health must be considered important when the impact of the model used is sensitive enough to make a difference. Errors however should not impact adversely where wide variation exists in classification methods.

"The visibility of the different tissue layers might be limited," Bloemen et al (2011)

Visibility difficulties cannot be excluded from some of the more difficult callus lesions seen in podiatry. When it comes to photographic observation of wounds associated with pressure ulcers, some of the difficulties may appear different,

"First, a large proportion of photographs were not stageable, even by the experts. This was often because eschar[‡] covering the wound made it impossible to judge the extent of tissue involvement." Localio et al (2006)

Soni (2013) chose to use pre-prepared photographs from known sources as a control, but only required observers to indicate which type of lesion they represented i.e *corn or callus, melanoma, fissure or verrucae*. The students in the nominal classification project had to differentiate one type of lesion into a group Typed 1 to 4. This demanded a greater degree of interpretation from the descriptor as opposed to comparison with general pictures of lesions. The difference in complexity between the two studies implies that a descriptor allied to a nominal scale is more difficult to interpret than by comparative photographic observation.

The first year (unskilled students) performed least well for Weighted Quadratic Kappa (WQK) / percentage (0.33 / 42%) compared with third year, semi skilled students (0.62/56%) for photographic lesions. The experts achieved a reasonable (0.79 /70%) outcome. The latter value allowed for low observations by two dermatologists. When these data were removed, the values increased to (0.88/83%). The experts were selected from a group of 36 podiatrists, and while each expert achieved >83% reliability for part 2 method, other podiatrists did not achieve the same level of accuracy. Weight quadratic Kappa for the group of 36 podiatrists returned (0.81/70%) - Appendix 8.A which strengthens the value of the observational system with photographic evidence alone.

Soni (2013) suggests that second and third year cohorts performed well with exposure to text based photographs, but, it would not be possible to draw extensive conclusions from Soni's work because the method was completely different, and statistics relied on percentage responses. The trend that lecturers performed better with photographic observation was evident and contrasts favourably with experts within this project and other research, Bloemen (2011).

The narrow range of possibilities with corns and callus might contrast favourably with the errors found in the nurse study. However, the nurses were selected from a wide variety of European countries where no pre-study training had been established. Absent prior training seems an open opportunity for error. Confounding errors arise more readily from photographs if descriptors used to judge lesions provide ambiguity. Bloemen (2011) demonstrated this with the subtle difference between percentage of fibrin to cover the wound versus area of epithelisation. Boundary definition and callus density within the lesion could well suffer similar errors.

A histogram (Figure 5.3) produced a bimodal frequency for a population of 90 observer raters for six photographic lesions, for students and all clinicians (biophysics engineer and dermatologists) used in the study, Table 4.1. Two student observers scored zero and one student managed to achieve 100%. This may well be down to a chance occurrence but could also be due to individual student success in observational aptitude. The student was female aged 22-30 years and came from the Third year cohort. Past experience was denoted as '*not given*' and so no correlation could be made with past knowledge, except more clinical field experience as one explanation.

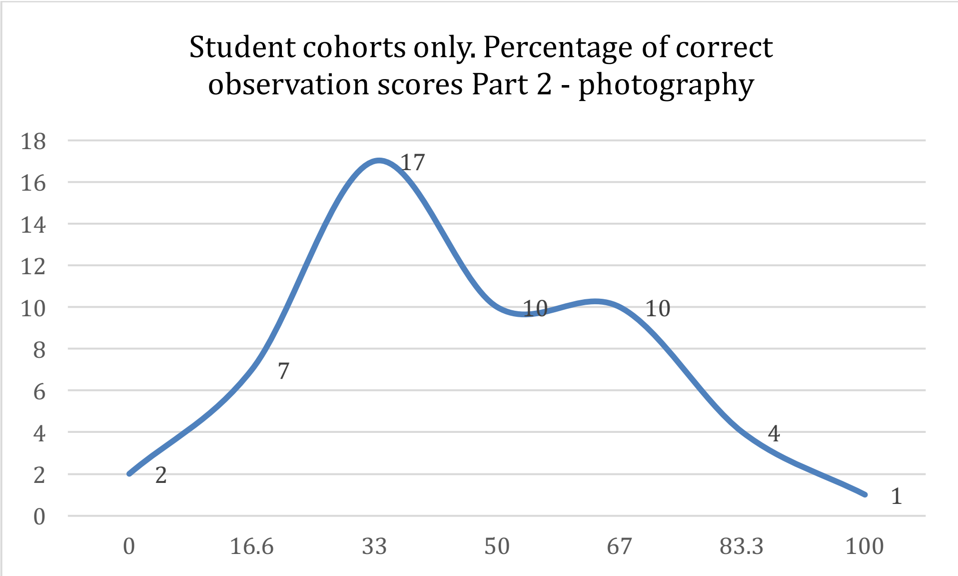

Figure 6.3.

Students cohort with skewed frequency distribution.

The inclusion of experts (dermatologists) provided an opportunity to consider the effect of observers unable to interpret the descriptors as well as podiatrists in the field of podiatry. A symmetrical Gaussian 'bell' shaped curve would be unlikely, even with higher numbers of qualified podiatrists, suggesting two sets of data would have different distributions. When the skilled clinicians were removed (figure 6.3), a single peak arose skewed left of centre, showing that majority of students, one-third, peaked around 33% correct observation. Without pre-observation education with descriptors the population of podiatrists, skilled or otherwise, would mostly likely demonstrate bimodal curves of distribution with majority able to score between 33-67% without tuition. There appears a gap around the median between those able and those less able. It was difficult to make absolute inferences as the population sample was not representative of a whole student population estimated at 1280 students (13 university centres). Using a Confidence interval of 5.6 the sample of 80 (6.3%) observers fall lower than an ideal sample of 236 or 18% for a confidence level set at 95%.

Direct comparisons with other studies cannot always be made as the type of Kappa statistic is usually not stated, or as in the case of Lacalio et al (2006), Inter-class Correlation Coefficient statistics were used.

Contrasting Part 2 method, where everyone was only exposed to photographic lesions, the experts raised their performance using WQK. 0.80 (70.2%), including 2 dermatologists, as opposed to 0.62 (56.1%) third year and 0.33 (41.9%) first year. By analysing this result it is clear that as skills develop, the observer reliability of the student increases. Soni (2013) found the gap between each student and the tutor (experts returned 96%) was small; second year (87%) and third year (91%). Comparisons cannot be made as the educational timelines compared to the student cohort in this study were different to those in this project.

6.5 Reliability across all parts of the method

While direct and indirect observation has been described, the use of surrogate illustrations was considered within method part 3; Figure 4.5, Table 4.3, as another form of indirect assessment and with controlled use of the classification system.

Comparison of the illustrated replication of a lesion, with photographic images and clinical observation, were tabulated (Table 5.2). There were notable patterns of difference and the Null H_o was rejected in each case.

The diagrammatic representation was placed into the method purely to test students' ability to observe shapes under controlled conditions. The results were predictable in that first years did less well then third years, who in turn did less well than qualified experts. When tested with a different skill group, 20 nurses performed nearly as well as podiatrists (0.84/77%).

Student podiatrists (first & third year cohorts), nurses and qualified podiatrists matched ten questions to the lesion chart Figure 4.1. Because of the perceived simplicity of the exercise, dermatologists were excluded. In retrospect simple exercises can offer information about perceptions of method. Irrespective of simplicity or difficulty such exercises should not be underestimated, as in the case of the dermatologists.

The idea behind this method was to control the classification of lesions initially by removing factors associated with visual problems associated with photographs. The difference for diagrammatic representation showed smaller variation between observers than other methods. This hardly seems surprising as the skills did not require specific clinical knowledge as in the case of detail photographs, or direct observation and complex changes associated at the EDJ level.

As the diagrammatic method was not appropriate to screen for observer's visual problems, the pre-entry test was excluded from the results. The respondent students and nurses performed badly (Appendix 6). The question was misleading, highlighting many low scores. Visual acuity testing would be better tested by a qualified optometrist. Furthermore, colour blindness was not accounted for. This area of weakness was independent of any skill based influence and should have been part of exclusion criteria.

In considering why a bioengineer bettered the dermatologists seems to be expressed by the view of one of the dermatologists; *"We just do not see much callus."* While in some ways this might provide an adequate explanation, dermatologists do see verrucae, hence an ability is assumed that the EDJ can be evaluated, or is of interest to this group. The bioengineer probably sees little callus but benefited from exposure in research at PhD level and above, and was able to follow the descriptor without difficulty. When diagrammatic lesion representation was conducted, a lay person (English teacher) with no formal scientific background completed part 3 method correctly. This finding suggests that the basis for clear comprehension not only lies behind questions, but interpretation based in reading the descriptor, and applying such criteria correctly makes for a better classification model.

With respect to the dermatologists, further explanation for poor performance might relate to insufficient time spent looking at the criteria and failing to understand the question due to over confidence or complacency – implied by one of the two dermatologists. The only way one can analyse this element of high skill – poor performance - would be to increase the number of dermatologists in the study, repeat the method and add more controls. The exclusion of dermatologists from the diagrammatic part provided a design flaw in the methodology. Some of the observer selection problems were mitigated by diligent selection of experts from an original cohort of 36 podiatrists, recruiting those scored 83.3% or more (Appendix 8.A).

On the basis of WQK the first years performed ***'moderately'*** and the third years ***'substantially'*** for a percentage difference of 2%.

6.6 Descriptors

In order to interpret photographs, descriptors were created and expanded from the original Tollafield & Price (1985) study. Ideally the descriptors should be validated. Such validation could be achieved by a Delphi method but insufficient time was available.

For callus, the construct of each Type representing an incremental scale of adversity could not be shown, neither proven. A nominal based scheme was therefore accepted over an ordinal scheme. When it falls to validation, true validation cannot be assumed for the nominal classification system, only for the purposes of setting a level upon which students can be assessed. Validation was used in broad terms to ensure some uniformity or control against which responses could be compared, and to further limit the lesions to those that could reasonably be interpreted.

Validation would not be easy to achieve as there is no present system available that could establish a guarantee that one Type was unequivocally different to another Type. The exceptions would be where a Type 4 lesion was correlated to pain associated with EDJ damage. Epidermal thickness could be correlated to punch biopsy thickness measure where the method required graticule measurement under a microscope, (Tollafield et al 2001). Repeatability would offer a worthwhile extension to the project, while intra-observer reliability was only used by Bloemen (2011) in the material cited, which leaves room for further study. Meta-analysis is often important but relies on many studies following similar methods; most methods varied and the best that could be achieved had similar photographic designs and some statistics. Descriptors in existing studies relating to corns and callus appear to have no similarity to skin wounds.

It is accepted that brief descriptors appear easier to interpret than lengthy, multi compartmentalised text; i.e 1a,1b, 2a,2b. This is often found in orthopaedic classifications (Tachdjian 1972)[12] and Sgarlato (1971) simply increased the options associated with *shearing callus*[‡]. In studies where callus was not classified, textural changes in dental enamel, Skaare et al (2013) proved ambiguous. Descriptors are common to many studies

[12] Salter-Harris (1963) defined fractures through the epiphyseal cartilage in children based on radiographic appearances. A large part of orthopaedic classification relies on observer interpretation. This classification exemplifies the complexity that can arise with seven Types I, II, III, IVa, IVb, Va, Vb. Systems can provide general indications about trends, but variants within any system increase the difficulty in achieving a system to cover all eventualities. Salter-Harris embellished Poland’s (1898) similar classification which had four Types A-D. Source Tachdjian (1972).

associated with grading pathology. Given the complexity of designing components some detailed discussion is required.

Within the boundaries of this project, even when altering a single part of the descriptor, a negative effect could occur. The phenomenon was examined briefly due to variation within the wording between the two descriptors used. Table 6.1 highlights the different interpretations highlighting ‘density changes’ in the ‘A’ and ‘B’ descriptors (Chapter 4). Minor alterations were made to descriptor A – Type 2 lesion suggesting *the presence of density change*. In descriptor B, Type 2 only refers to ‘*sub epidermal haemorrhage’* which is entirely different, and relates to intra lesional damage. Type 4, for both descriptors maintain that this lesion has *variable density* or *concentration of keratin*.

Variation in descriptor ‘A’ caused a variety of different interpretations between experts who selected either Type 2 or 4. Student observers selected Type 2 (43%)/Type 4 (32%) similarly. Eleven student observers however went for Type 1 (20%) based on the descriptor indicating an absent border. The small changes within the rogue question, which should have had a border under normal expectations, would have been graded Type 4 within this classification approach. While this part of the project was accidental due to a drawing design, the flaw usefully allowed better consideration of descriptor discussion. Only relevant parts where the descriptor may alter the meaning have been

Type	Descriptor A (Summarised) used by Experts	Descriptor B (Detailed) used by students
1	No border…uniform keratin depth	…the deeper tissue changes are not involved as in type 2 or type 4
2	Border present or partially present with variable keratin depth. No discrete distribution of concentrated keratin evident… but **asymmetric density changes**…	…Areas of flaky skin, complicated with **sub epidermal haemorrhage** do not constitute a nucleus of tissue and should be disregarded..
3	Concentrated keratin plugs, or in groups of lesions…diameter less than 4mm	…discrete circumscribed area, but may be elongated..
4	Border definition present **with variable keratin depth** but demonstrating discrete distributions of concentrated keratin greater than 4mm within the callus	The callus will have a circumscribed symmetrical or asymmetrical **area of greater depth, ridge of greater concentration anywhere within the callus**.

Table 6.1. Descriptor variations highlighted in Part 3 - Method.

Included in Table 6.1, based on density and keratin depth. The expert observers came up with two possibilities with an equal chance of correct agreement compared to the other lesions. Because of the ambiguity in the descriptor and question, removal of question 9 pertaining to lesion (I) negated the effect. Alternatively, by making the expected answer equal to 2 or 4 ensured that the same value existed. Different contingency tables were created for weighted Kappa represented in Table 5.10. The effect associated with these alterations has been incorporated into the findings.

The descriptor had minimal effect on the experts or non experts. First year (unadjusted – 0.50 / adjusted 0.46), third year (unadjusted – 0.57 / adjusted 0.57), Experts (unadjusted – 0.94 / adjusted 0.94).

Interpretation could lead an observer to believe that any discrete distribution of concentrated keratin greater than 4mm (Simplified descriptor A Table 4.2(i) could be viewed alongside Type 1, within the detailed descriptor B in Table 4.2(ii). Border definition must also be considered.

Most classification systems do not develop from testing or validation but emerge into health science lexicon as *ad hoc* methodology. The classification of callus currently existing from 1978 had not been established by validation, neither reliability or repeatability measured. Staging is different from a nominal classification such as cold – medium – hot, each being descriptions of temperature but allow error between extremes. *When is cold not cold?* The use of descriptive statistics using continuous data i.e 10, 15, 20 degrees Centigrade would be more accurate and can be measured by validated methods – namely a digital thermometer.

Where pathology changes incrementally, most classifications use observational interpretation and any unclear distinctions can lead to error. In each of the callus classifications, based on DuVries (1978), Tollafield (1985), Merriman (1987) and Campbell (2002), no study was made to determine the accuracy of the descriptors. The opportunity for narrative variation between each assumptive classification is evident because the authors offered different ideas about what should equate to a nominal scale. The nominal scale differs from an ordinal scale in that each graduation does not necessarily imply proportional severity. *Is a seed corn worse than diffuse callosity?* The answer *'it may be, but not necessarily'* one may be more symptomatic than the other under specific circumstances. Aetiology cannot be considered in any detail because of the breadth of study required.

Callus is exposed to a variety of causative factors and the supposition that a grade can be applied still attracts subjectivity. Herein lies the dichotomy of an assumption of origin which forms an impact on clinical practice. Whiting (1997) provides evidence of missed opportunity for establishing aetiology that in turn requires quality diagnostic imaging such as ultrasound, MRI or even biopsy.

The effect of misinterpreting the information was recognised by Beeckman where it was clear nurses required a tutorial commencing the project. The dermatologists in this corn/callus study failed to consider the criteria correctly when applied to photographs. When students and nurses were asked to provide responses, errors arose by copying or discussing decisions between colleagues rather than working independently. This has been cited as altering the reliability values positively. On the contrary, data showed from this project that students with anonymised numbers would probably have sat close together and equally returned an incorrect response, so this would still be classed as independent as no consensus would have been engaged. Experts could not exchange views and were truly independent, isolated and anonymous to each other. This aspect is important and supports the value of expert panels as useful controls.

The student observers used the medium of descriptors to make a judgement either as an unskilled or semi-skilled observer. Ideally as the descriptor improves, observational scoring will improve. Skill will certainly outweigh other factors although chance guesswork does play a factor where uncertainty lingers. The objective behind the descriptor must remove as much guesswork by identifying the weak elements behind lesion representation.

Chapter 7

Conclusion

No similar studies evaluating reliability of corns and callus observation set against a classification score system exist with English language references. Comparative evidence used indirect observational photographic methods associated with wounds, ulcers and burns. Classifications, including the one exemplified in this project, have not been validated, as most have been engineered as bi-products from other research studies. The numerated form of classification often adopts six stages, types or grades. The descriptor(s) used in the project were limited to four unrelated (nominal) stages. This was simplistic and did not account for changes arising with callus presentation and therefore two further options would be recommended (Appendix 10).

It is unlikely that every permutation of callus can be accounted for in a classification scheme, so it may only be possible to consider generic features based on border symmetry and prominence, density variations and thickness. Localisation of lesions supports, but does not participate in classification. The assessment of deeper epidermo-dermal junctional changes cannot always be reflected by observation, but debridement improves any such evaluation where keratin layers are reduced. Classification errors will always arise from photographs and reliability will be inconsistent and depend upon the quality of pictures of lesions, correct interpretation of the classification method, type of pathology and need for histological validation, which is not available to general podiatry.

The use of Cohen Kappa k offered useful statistical analysis in keeping with other studies. Kappa provided a valuable method when considering reliability rather than using percentage accuracy. Percentage was not considered reliable for inter-observer classification. Ideal measurements include $k > 0.61$ - *'substantial'* and $k > 0.81$ - *'Almost perfect'*.

This project set out to consider the reliability of direct observation and indirect observation using photographic plates. Student inter-observer reliability, matched to results of a group of podiatry experts, varied within the three parts of the method; diagrammatic illustrations of callus, photographic plates and clinical observational scoring using. Overall student reliability k <0.61 and therefore did not meet a level of skill associated with experts.

Students did show improvement when confronted with patient lesions in a clinical environment, performing better than when using photographic evidence alone. Debridement improved the accuracy against expert panel scores; up from WQK first years (*k* 0.44 to 0.56) and third years (*k* 0.45 to 0.54). There was no significant difference between the two groups of students. Students showed similar results to the experts where the experts appeared more accurate with pre-debrided lesions; range *k* 0.54-0.59.

Third year students performed better than first year student with photographic and diagrammatic parts of the method respectively; (*k* 0.73,0.62), first year; (*k* 0.58,0.33). The element of skill, based on a period of clinical or field experience, was found to be relevant for the first two parts of the method, but not the last part. Third years were perhaps better at theoretical application than actual application which might be credited to a greater period of study within a healthcare course. When it came to clinic, the results were unequivocal.

While the descriptor was not tested as a separate entity, some sensitivity in descriptor usage was analysed. Weaknesses such as consistency of terminology, clear use of border appearance, density definition, lesion shape and colour were found and descriptor clarity could be improved. Work is required with the use of more podiatrists acting within a Delphi Study. Re-testing with qualified podiatrists and introducing a teaching module might improve general reliability. The value gained from the evidence using students in the study could aid new approaches to teaching observational skills for callus.

Classification Types would benefit from six options to cover flaky dry skin and account for diffuse callus with asymmetric, non concentric dense lesions within any epidermal thickening (Appendix 10). Ulcers or erosions, should be avoided, unlike Merriman's (1997) classification, which mixed callus and ulcers.

Photography as a medium for observation has limitations, some of which arise from descriptors (Chapter 6, 6.5). Sufficient evidence exists that photography cannot be excluded as a means of communication and record annotation. Lesions appear more reliably classified when debrided, and when observed directly in a clinical environment. However, in the hands of experienced podiatrists photographic reliability can be encouraging. Photographic reliability within the podiatry population may range from 66-83% at best, with outliers depending upon the complexity of the lesion. However, direct observation does appear to be more reliable in the hands of lower skilled students in podiatry when compared to photography.

The classification method as described was not truly validated, even similar studies used the term validity. This would be contested. Validation in this study purely related to setting controls against which students could be tested and would not be regarded as proper validation. Outside histopathological validation, other than with the establishment of new tests, the best study currently might lead toward greater sensitivity and specificity within the system; knowns must be considered that are uncontested before this can be achieved. Ultrasound is still in it's infancy from the student researcher's viewpoint and correlation studies are still required.

Diagrammatic illustrations as an aid for observers were difficult to categorise and were not part of a rigorous test, nonetheless, illustrations appeared useful to support descriptors and therefore could help annotation in patient records. This might be more valuable where photographic capture of lesions was not possible.

No assumptions can be made about skill or ability outside the field of podiatry. While these factors are important, motivational attitude will cause poor results and affect outcomes. However, two dermatologists do not constitute a reliable study size from which conclusions can be drawn.

Although not tested in this study, training does appear to contribute to the effectiveness of any classification; Beeckman's (2007) experience, 'how to use' and 'interpret' a descriptor is as important as the design when constructing either a nominal or ordinal scale classification method. Training in classification methods could be included within undergraduate podiatry courses where this is not the case, suggesting reliability of such methodology reaches a value of k = or >0.61.

Histological analysis provided by surgical excision is required to sample the more complex epidermo-dermal junctional (EDJ) changes to truly validate lesions. In the absence of this option, podiatrists should use location carefully with the classification while the traditional broad descriptions can still be used judiciously in light of these findings. The veracity behind neuro-vascular corn, or vascular corn has not been tested in this project, but any future work would need to consider pathology and the effect on the EDJ.

Small variations need to be accounted for in any future design for descriptors to avoid potential errors affecting reliability. This project provided a significant learning opportunity, indicating that the 2013 descriptors still require improvement. Nominated scales should cover a sufficient range of descriptors to avoid obfuscation where some lesions do not fit the descriptor, or lead to ambiguity. A revised nominal classification could replace the previous system with consensus. Depending upon how well the classification system was received, this could contribute to improve clinical record annotation when combined with accurate location, pain and disability P.R.O.Ms[13].

The most important conclusion from the project should highlight that corns and callus have a wider aetiology base that should be accounted for with other methods of assessment. That debridement is useful is not questioned. However, the literature now demonstrates that debridement as a treatment might benefit from critical debate within the podiatry profession. As a diagnostic aid and chart of progress within the presentation of foot pain, such a philosophy is less likely to be challenged externally than as a poorly ineffective, short lasting treatment.

The true aim of classification of corns and callus is to present a stronger argument that many lesions represent pathology that if left unaddressed will add to patient symptoms leading to pain and disability; in this regard Grouios (2004) is correct;

"…but failure to manage serious skin changes can lead to disabling pathology."

[13] Pain and disability can be measured by a number of Patient Related Outcome Measures often called P.R.O.Ms. although simpler systems exist such as Visual Analogue Scale (VAS) based on whole numbers 0-10 or 0-100

APPENDICES

Appendix 1. Consent Form

To determine the validity of a classification system for plantar callus.

INFORMATION SHEET (student podiatrists)

You are being invited to take part in this study 'diagnostic skills acquisition in a controlled environment. Before you decide to take part it is important that you understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with me if you wish. Please do not hesitate to ask if there is anything that is not clear or if you would like more information.

What is the study about?

The purpose of this study is see if a pre-existing classification system can be applied to keratin foot lesions (corns, calluses and keratoma) and determine the interpretation and reliability of each observation.

Why I have been approached?

You have been asked to participate because as a student your learning skills have not be completed at this time, and this allows you to act as a subject observer because of the variable skills acquired at this point in your course.

Do I have to take part?

It is your decision whether or not you take part. If you decide to take part you will be asked to sign a consent form, and you will be free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect your own studies.

What will I need to do?

If you agree to take part in the research you will be invited to

a) complete several forms with prepared information and diagrams with accompanying text, then look at colour plates of lesions and identifiy them anonymously with the aforementioned diagrams.
b) complete as above (a) and observed debrided callus lesions on the sole of a foot as directed by your supervisor and classify the lesion. Your completion sheet will be anonymous. In all cases multiple students will be asked to complete the same task. The information will be recorded but again the names of all participants and patients will be anonymous

Will my identity be disclosed?

All information disclosed within the interview will be kept confidential, except where legal obligations would necessitate disclosure by the researchers to appropriate personnel.

What will happen to the information?

All information collected from you during this research will be kept secure and any identifying material, such as names will be removed in order to ensure anonymity. It is anticipated that the research may, at some point, be published in a journal or report or similar publication for education purposes. However, should this happen, your anonymity will be ensured, although it may be necessary to use your words in the presentation of the findings and your permission for this is included in the consent form.

Who can I contact for further information?

If you require any further information about the research, please contact me on or go to my website page www.consultingfootpain.co.uk under clinical portal where further information is available covering the original classification system

Appendix 2. Demographic data *(student observer population)*

Group (category	*Age range*	*First year*	*Second year*
Group 1	18-21	*40.6% (13)*	*25.0% (6)*
Group 2	22-30	*25.0% (7)*	*29.2% (7)*
Group 3	31-50	*31.3% (11)*	*45.8% (11)*
Group 4	51 and above	*3.1% (1)*	*0% (0)*

Table 2.A.

Age (range expressed as Group 1-4)

The age of students is typical for training cohorts in podiatry. Based on recent data from the Society of Chiropodists & Podiatrists (2015) the mean age at entry is 32 years of age.

Experience	Deg	Sci	Non sci	Profession Qualification	Non-Professional Qualification	Apprentice	No formal skills	Mixed	Not answered
First Yr.	15.6% (5)	18.7% (6)	12.5% (4)	9.4% (3)	0% (0)	0% (0)	21.9% (7)	9.4% (3)	12.5% (4)
Third Yr.	8.3% (2)	20.8% (5)	12.5% (3)	25% (6)	8.3% (2)	0% (0)	4.2% 1)	4.2% (1)	16.7% (4)

Table 2.B.

Previous experience divided into seven categories and one mixed

Legend: Sci. = science. Deg. = degree

Data was insufficient to draw any conclusions. Neither age nor previous experience provided an advantage in regard to rating lesions. Females dominated the two groups and were consistent with the expectations for podiatry recruitment.

The clinical exercise was equally distributed with ten students from each year with 7 males (third year) and 5 males (first year). More females (81%) than males (19%) entered the study.

Appendix 3. 10 Colour Plates - Direct Observation

The 10 colour plates show the five feet (three cases) before and after debridement. A-E paired feet with their relative lesion Types 2 and 4 predominate and tend to cause more notable symptoms for patients.

Pre-debrided plantar lesions		Post-debrided plantar lesions
	A	
Type 4		Type 4
	B	
Type 2		Type 2

	**C**	
Types 2		**Types 2**
	**D**	
Type 4		**Type 4**
	**E**	
Types 4		**Types 4**

Appendix 4. Indirect Observation – 6 Colour Plates

Six photographic images used Method 2 for students and experts

Method 2 - Corn or Callus lesion		Clinical description and classification
	3	Type 3 – Case 1 Corn enucleated cleanly with peripheral thickening at edge. No associated callus present.
	1	Type 1 – Case 2 Diffusely spread callus with undefined border
	4	Type 4 – Case 3 Plantar phalangeal lesion with extravasated material at joint line forming nucleated mass and deeper tissue change associated with damage

	2	Type 2 - Case 4 Border more notable at the antero-medial aspect under second metatarsal. No alteration of density is noted throughout the callus. Undebrided.
	4	Type 4 - Case 5 Deeper damage where the nucleus is asymmetrically located with variable depth changes. Lesion debrided.
	4	Type 4 - Case 6 Well defined border partially debrided with central mass demonstrating damage traditionally known as a neuro-vascular corn based on intractable nature of management of the lesion.

Appendix 5. Experiential data – student cohorts

Basic data was collected anonymously from students and shown in Chapter 5 (results) table 5.1. The so called 'groups 2-3' seen below, relate to the three methods used and pre-dated the finalised version which was not used.

Study Reference ________

Please Vertical (Value) Axis owing information and submit this with the Pre-test chart. Please tick in the column for the relevant groups shown. Ensure each side has your given reference number

---

Gender of student observer: M / F (*encircle*)

Year: First / Third (*encircle*)

Age Group	**Tick one only**	**EXPERIENCE Previous experience only for groups 2-4**	**Tick best fit**
18-21		a. Previous degree (any level)	
22-30		b. Scientific background	
31-50		c. Non-scientific background	
51 and above		d. Professional (qualification dependent)	
		e. Non-professional (no formal qualification)	
		f. Apprenticeship skilled including FCA	
		g. No formal skills	

Experience		**FY**	**%**	**TY**	**%**
Previous degree	a	5	15.6	2	8.3
Scientific background	b	6	18.7	5	20.8
non scientific background	c	4	12.5	3	12.5
Professional qualification	d	3	9.4	6	25
Non professional	e	0	0	2	8.3
apprentice	f	0	0	0	0
No formal skills	g	7	21.9	1	4.2
mixed	h	3	9.4	1	4.2
No result given	0	4	12.5	4	16.7
Total		32	100	24	100

Table 5.A Breakdown of student past experience

FY. First Year, TY. Third Year

Appendix 6. Pre-test Observation for Students and Nurses

Students were asked to compare eight boxes with the Lesion Chart (Figure 4.1) and match those which repeated. This part of the method was subsequently dropped because the objective fell short of the intentions as described in chapter 6.

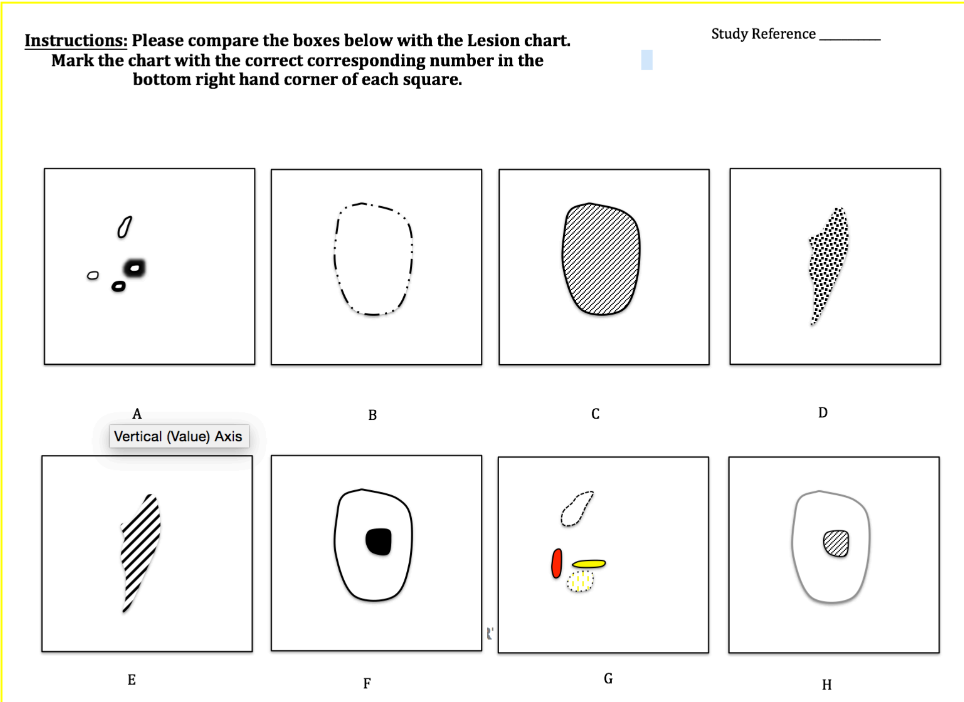

Figure 6.A.

The test does not reflect gender, age, experience or qualification for 77 observers. The **pre-test** was piloted with insufficient observers. The intention was to serve as a method of excluding observers expected to return a high percentage of correct matches.

The conclusion to the brief study demonstrates that the question was misread in that the contents of the 4 images boxed should replicate only 4 of the 8 images given in the example against the Lesion Chart (Figure 4.2). Where shapes alone were compared, observers improved despite being incorrect. Those who did not select the box or shape ultimately misunderstood the exercise and went for a different interpretation. The instructions could have read 'select 4 of 8 images' but this would have defeated the exercise based on correct assimilation of data.

It is hypothesised that people who undertake puzzler exercises would be more likely to score accurately and there is a common frequency for misreading questions. Additionally, in both groups of nurses and students, it was not unusual for observers to share information to the extent that incorrect answers were copied. Simple exercises often show that assumptions are incorrect and this observation was repeated for the two dermatologists who volunteered to take part.

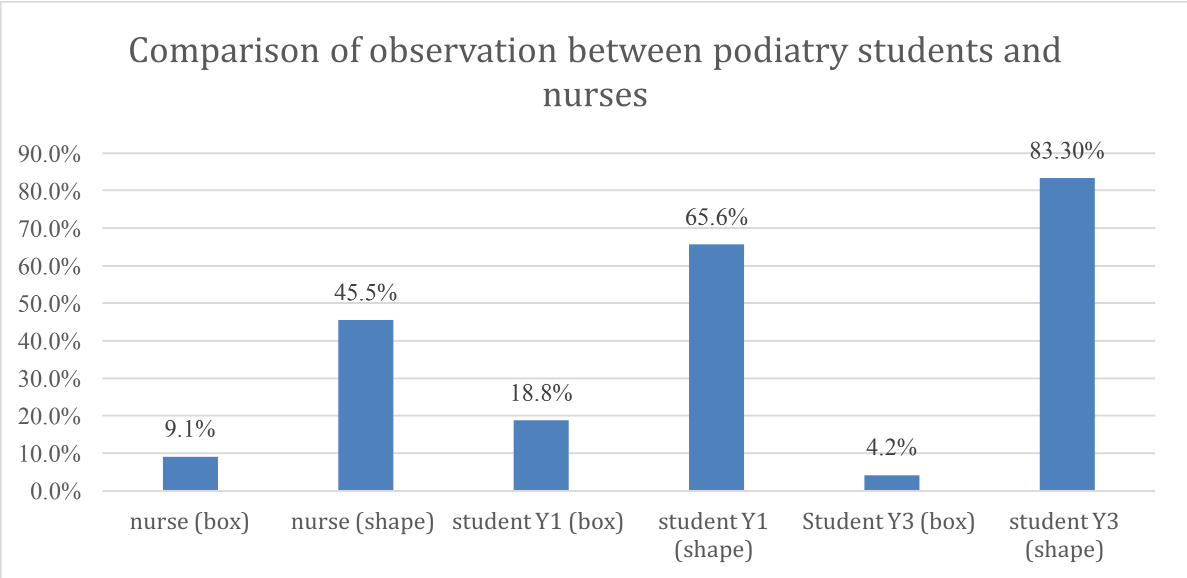

Figure 6.B.

The histograph illustrates different outcome data (%) when students and nurses were set a task to match the diagrammatic contents of boxes.

Appendix 7. Photography versus diagrammatic lesion impressions

The frequency of correct observations for each whole group of observers was compared for parts 1 and part 2 of the method where the lesions correlated to lesion type; i.e diagram type 4 with photo of type 4. This does not provide a true correlation relationship but is used to identify trends in lesions selected by observers as in Table 5.5. The purpose of the question was to find out if certain lesions were easier to identify.

Diagram	Photo
A	4
C	1
D	2
G	5
J	3

Table 7.A.

Matched groups from two parts of the method

Lesion	Diagram	Photo
1	11.9	20
2	13.6	75
3	94.9	28.3
4	76.3	48.3
4	76.3	75

Table 7.B.

Percentage (%) observer response with matched lesions for diagrams and photos.

Five lesions were matched from Part 1 - diagram (59), and Part 2 - photographs (60)

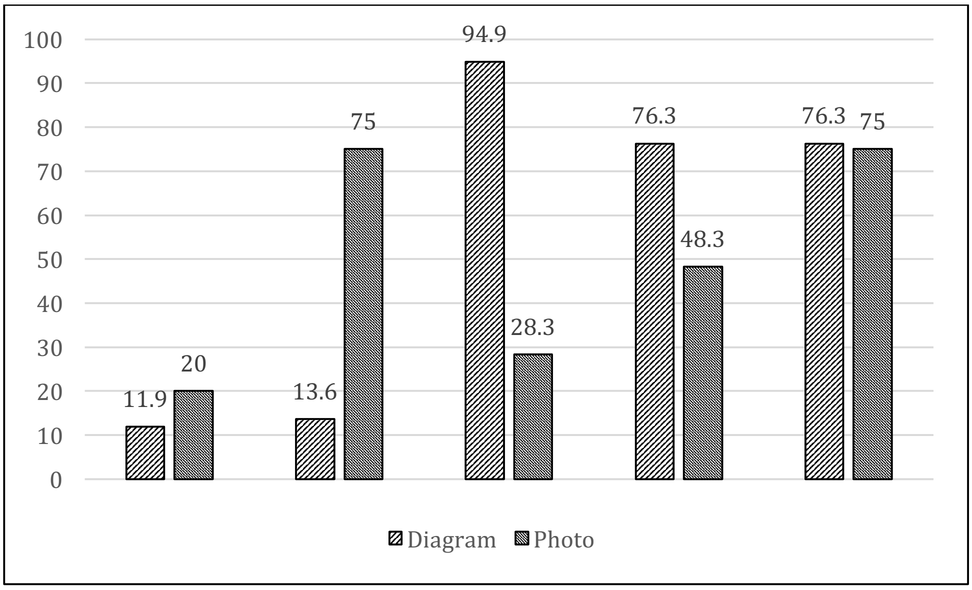

Figure 7.A.

Comparison between common lesions for Part 2 & 3 Method[14]

***Left to right:* lesion types 1-2-3-4-4**

The benchmark was arbitrarily set at 75% although benchmarks discussed in the Chapter 2 ranged from 66-83%. Three diagrammatic and 2 photographic lesions met this benchmark. From the photographic exercise, lesions type 2 and type 4 appeared easier to match; from the diagrams, lesion type 3 and type 4. Two lesions were debrided but the scores suggested this provided no additional benefit suggesting a Null H_o could not be rejected. It was not until part 3 of the method was carried out that the use of debridement before and after observation could be analysed robustly.

[14] Relates to Table 5.5 in Chapter 5 p.65

Appendix 8. Raw Data from Expert Podiatrists

Figure	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
1	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	4	3	3	3
2	1	1	1	1	1	1	1	0	4	1	1	1	1	1	1	1	1	1	1	2
3	4	2	4	4	4	4	4	4	4	4	4	2	4	4	4	4	4	4	4	4
4	2	1	2	1	2	0	2	1	2	2	1	1	1	1	2	1	1	2	1	1
5	4	4	4	2	4	4	4	4	4	4	4	2	4	4	4	4	2	4	4	4
6	3	3	4	4	4	2	4	3	4	4	3	2	4	3	3	3	3	4	4	4

Figure	**21**	**22**	**23**	**24**	**25**	**26**	**27**	**28**	**29**	**30**	**31**	**32**	**33**	**34**	**35**	**36**
1	3	4	2	3	3	4	3	3	2	3	3	3	3	3	3	3
2	1	2	1	1	1	1	1	1	1	1	1	1	1	2	1	2
3	4	1	3	2	4	4	4	4	4	2	4	4	4	4	4	4
4	2	4	1	1	2	1	2	2	1	1	2	1	2	1	2	1
5	4	3	4	4	4	4	2	2	2	4	4	4	4	4	4	3
6	4	4	3	4	4	4	4	4	3	4	4	3	3	2	3	4

Table 8.A. Raw data for 36 Podiatrists from e-mail responses

Qualified Podiatrists (n=36) selected for the study Photographic observation. Those willing to contribute to the expert part of the study were included. The objective was to meet at least 83% accuracy or more. 100% marked in red.

Eight podiatrists scored 100% (22%). This has been computed to Weighted Quadratic Kappa. Only subjects 3,4,7,19,21, were selected while others who scored correctly did not consent for inclusion.

Appendix 9. Validating data

Location	**Expert Observer**	A	B	C	D	E	F	G	**Dominant**
Met.4/1R	Pre/post	2/4	2/4	4/4	2/2	4/4	2/3	2/2	2/4
Toe 5/1R	Pre/post	1/4	1/0	0/0	4/1	0/0	0/0	3/1	None
PlPh1/1R	Pre/post	1/1	0/0	0/0	1/0	1/0	1/0	1/0	1/none
Old Tx/1R	Pre/post	x/x	x/1	0/0	0/0	0/0	0/0	1/0	None
Met.1/1R	Pre/post	1/1	0/0	0/0	0/0	1/0	1/0	1/0	1/none
Met.1/2R	Pre/post	4/4	4/4	4/4	2/2	4/2	2/4	4/4	4/4
Met.3/2R	4Pre/post	4/4	4/4	4/4	4/4	4/4	4/4	4/4	4/4
Apex 2 /2L	Pre/post	2/4	4/4	4/4	0/4	3/3	2/0	4/4	None/4
Met.4/2L	Pre/post	4/4	4/4	4/4	4/4	4/4	4/4	4/4	4/4
Met.1/3R	Pre/post	1/1	0/0	2/1	1/2	1/1	0/2	1/2	1/none
Met.2/3R	Pre/post	2/2	2/1	2/2	2/2	2/2	2/2	4/2	2/2
Met.3/3R	Pre/post	2/2	1/0	2/2	2/0	3/2	2/2	4/2	2/2
Met.5/3R	Pre/post	1/1	3/3	0/3	0/3	0/2	0/2	0/2	None
PlPhM1/3L	Pre/post	1/1	0/0	0/0	0/0	0/0	0/0	0/0	None
PlPhL1/3L	Pre/post	1/1	1/1	0/0	1/1	1/1	0/0	1/1	1/1
Met2-3/3L	Pre/post	2/2	2/1	2/2	2/2	2/2	2/2	4/2	2/4
Met.5/3L	Pre/post	1/1	2/3	0/3	0/3	0/2	0/1	1/1	None

Table 9.A. Controls & Validation

Expert assigned scores for student observer comparisons by dominancy – seventeen lesions.

Index

Met. = Metatarsal. 1-5 location of lesion under metatarsal (plantar), **PlPh** = Plantar phalangeal (great toe), **Old Tx.** = where known injury or treatment has been previously performed

Apex = refers to end or tip of lesser toe 2-5, **R** = right foot, **L** = left foot, **Pre** = pre debridement, **Post** = post debridement, **Met.3/2R** = plantar third metatarsal on case 2 right foot.

Scores: x -marked unassigned, 0 - no lesion recorded 1 - light callus no border 2 -callus with border / density change 3 -isolated corn 4 -callus with deep organised change or tissue damage.

Appendix 10. A six option nominal classification recommended

The findings from the research are concluded with the conception of a revised grading system based on six rather than four Types. This has been discussed in the conclusion chapter 7. The diagrams and descriptors have been developed from the elements of weakness within the original descriptor used for the project and the previous descriptor used by Tollafield & Price (1985). Attention had been paid to dry skin, borders and density changes within callus. The classification is designed for plantar surfaces of the foot which includes the plantar pulp of toes but not the heel. The heel has a range of different presentations which makes the location a large area for many variants to arise which do not always conform the plantar metatarsal or toe areas uniformly. Lesser toes (2-5) could be included in the classification but because of H. molle[‡] such distinctions have be left out presently.

TYPE	DESCRIPTOR
1	***Dry skin***. Flaky, not true thickening. Striae may be wider
2	Epidermal thickness poor or no border. ***No density changes within***. Background erythema occasionally present
3	Well defined 'button like' or ***partially defined border*** with epidermal thickness uniform through. Variant 'Pinch' callus on edges of plantar skin & toes. No epidermal-dermal junctional damage. Petechiae accepted or pinch extravasation.
4	***Well defined OR partially defined border*** with epidermal thickness not uniform through. ***Density depth is variable*** but no epidermal-dermal junctional damage.
5	Small seed like areas of separate identity without background callus except slightly thickened border.
6	***Well defined border*** with epidermal thickness with ***identifiable density often concentric but maybe eccentric***. Could take up small or larger part of surrounding callus. Epidermal-dermal junctional damage; extravasated

Table 10.A.

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